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PHD

The impact of National Health Service patient medicines helpline services upon service users and healthcare organisations

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Award date:
2020

Awarding institution:
University of Bath

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The impact of National Health Service patient medicines helpline services upon service users and healthcare organisations

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A thesis submitted for the degree of Doctor of Philosophy

University of Bath

Department of Pharmacy and Pharmacology

April 2020

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CONTENTS

Acknowledgements

I would like to thank my supervisors, Matthew Jones, Abbie Jordan, and Jenny Scott. It has been a pleasure to work with them, and they have been extremely supportive throughout this process. I have learnt a great deal from them.

I would also like to thank all of the people who took the time to participate in my studies. I would also like to thank the pharmacy professionals who helped to recruit study participants via their helpline services.

Finally, I would like to thank the University of Bath for the studentship which funded the research in this thesis.

Abstract

Background: Patients often experience changes to their medicines regimen while they are in hospital, and it is healthcare policy in the UK to ensure that patients' medicines are managed optimally after discharge from secondary care. However, research suggests that a substantial proportion of patients who have been discharged from hospital subsequently experience medicines-related problems and require support. Patient medicines helpline services (PMHS) have been set up by some National Health Service (NHS) Trusts in England, with the aim of providing medicines-related support to discharged patients. However, to date, little high-quality research has been conducted to examine the impact of PMHS upon service users and healthcare organisations.

Aims: The aim of this doctoral research was to address the following question: *What is the impact of National Health Service patient medicines helpline services upon service users and healthcare organisations?* In order to achieve this, the RE-AIM framework was used throughout the research. RE-AIM comprises five dimensions which are considered important for evaluating the impact of interventions (*Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance)*.

Methods: A mixed-methods approach was adopted, and five studies were conducted. In study one, an online survey was sent to pharmacy professionals at all 226 acute, mental health, specialist, and community NHS Trusts in England in 2017. Its aim was to obtain key data concerning the provision and usage of PMHS in NHS Trusts in England. Studies two and three were systematic reviews. Study two systematically examined the available literature regarding the effectiveness of medicines information services for patients and the general public. Study three systematically examined the available literature regarding the characteristics of users of PMHS, and the types of enquiries they make. Studies four and five were qualitative. Study four explored thirty-four pharmacy professionals' perceptions and experiences of providing PMHS, and its data were analysed using Framework Analysis. Study five explored forty service users' experiences of contacting PMHS, and its data were analysed using Inductive Reflexive Thematic Analysis.

Main findings: The findings suggest that PMHS have the potential to provide timely medicines-related support to patients and carers when they are feeling vulnerable during the transition from secondary to primary care. Additionally, PMHS are perceived as effective and valued from the perspectives of pharmacy professionals who provide them, and patients and carers who use them (e.g., satisfaction ratings are excellent, and users typically rate that the advice was followed). However, the evidence regarding the effectiveness of PMHS is limited by primarily consisting of subjective experiences and perceptions (e.g., survey and interview data) rather than hard outcomes (e.g., symptoms, disease recurrence, readmission rates). The findings also show that, despite their perceived benefits, the limited adoption, implementation, and reach of PMHS hinders their overall impact. For example, approximately only fifty percent of Trusts provide this service, and of those that do, on average only five enquiries are received per week per Trust. Additionally, the availability and promotion of extant PMHS could be improved. The limited adoption, implementation, and reach of PMHS is largely a consequence of limited resources and staffing to adequately provide this service. However, despite this, the findings suggest that once adopted, PMHS are likely to become a relatively stable service for NHS Trusts.

Conclusions: Based upon the findings of this doctoral research, practice recommendations have been made to improve the delivery of extant PMHS, in order to provide a more valued and efficient service. This has largely focussed upon improving the availability and promotion of PMHS, and for pharmacy professionals who provide a PMHS to share their learning with the wider MI community regarding ways to provide a PMHS with limited resources. However, since PMHS are currently provided suboptimally (e.g., they are only provided by half of NHS Trusts, and they are provided in a way that does not meet national standards), and since research has not been conducted to establish their cost-effectiveness, another recommendation is for stakeholders to consider the best way to support patients with their medicines following discharge from secondary care. Thus, research recommendations from this doctoral research focus upon exploring the future of PMHS, and establishing the best way to support *all* patients who need help with their medicines following discharge from secondary care, which is efficient and cost-effective yet without diminishing quality and perceived value.

List of abbreviations

A&E	Accident and emergency department
AHSN	Academic Health Science Network
CA	Conference abstract
CINAHL	Cumulative Index of Nursing and Allied Health Literature
DI	Drug information
FA	Framework analysis
GP	General practitioner
GPhC	General Pharmaceutical council
HCP	Healthcare professionals
HES	Hospital Episode Statistics
LE	Letter to the editor
MI	Medicines information
MISGP	Medicines information services for the general public
MUR	Medicine use review
N/A	Not applicable; no relevant data were found
NHS	National Health Service
NMS	New medicines service
NR	Not reported
PMHS	Patient medicines helpline service
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PRISMA-P	Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols
PROSPERO	International Prospective Register of Systematic Reviews
PS-BR	Study published as a brief report
PS-PR	Published study in a peer-reviewed journal
QoR	Quality of reporting
QoSD	Quality of study design
RE-AIM	Reach, effectiveness, adoption, implementation, maintenance
RoB	Risk of bias
RPS/RPharmS	Royal Pharmaceutical society
RRA-EP	Retrospective review of answers by expert panel
RRE	Retrospective review of enquiries
SD	Standard deviation
SSP	Cross-sectional survey of service providers
SSU	Cross-sectional survey of service users
TA	Thematic analysis
TCAM	Transfers of Care Around Medicines
UK	United Kingdom
UKMi	United Kingdom Medicines Information Network
USA	United States of America
WHO	World Health Organisation
WM	Weighted mean

List of figures

List of tables

Chapter 1: Structure of thesis

1.1 Overview of Chapter 1

This introductory chapter provides a summary of the doctoral research, including the overarching research question being addressed, and the chapters comprising this thesis.

1.2 Summary of doctoral research topic

National Health Service (NHS) policies regarding hospital discharges within the United Kingdom (UK) predominantly focus upon the issue of delayed transfers of care, with the aim of discharging patients as soon as possible (1-4). However, although rarely mentioned in NHS England and Department of Health policy documents, it is also essential to improve the safety of transitions for patients between different healthcare services and settings (5, 6). A suboptimal transition from hospital to home can be risky for a patient, and medicines-related problems may result in rehospitalisation, adverse medical events, and even death (7, 8). Hospital discharge has the potential to be a confusing and/or risky period for patients who have recently experienced changes to their medicines. Many patients leave hospital with gaps in their knowledge about their medicines (9-14), and a sizeable percentage of patients subsequently experience medicines-related errors and require support with medicines-related problems (15-22).

Patient medicines helpline services (PMHS) have been set up at some NHS Trusts in the UK, with the aim of providing an information and advice service to recently discharged hospital patients and their carers who have questions or concerns about the patient's prescribed medicines. Providing a PMHS accords with healthcare policy recommendations regarding the importance of not only providing patients with information, but also giving patients the opportunity to *seek* information about their care (23, 24). For example, providing a PMHS accords with World Health Organisation (WHO) policy, which states that offering information on medicines via Medicines Information (MI) centres, and providing public education about medicines, are essential interventions to promote the rational use of medicines (23).

Despite the first PMHS being established in 1992, prior to this doctoral research, PMHS had not been evaluated in a rigorous way. The small number of studies that had been published were mainly service evaluations conducted by providers of PMHS who had evaluated their own service, and therefore may be biased (e.g., selection and measurement bias) and lack generalisability (25-28). Findings suggested that service users are typically satisfied with the service, and that PMHS may provide an avenue for improving services within the Trust (e.g., improving discharge summaries, based upon the content of PMHS enquiries). Additionally, two surveys had been conducted to establish the provision of PMHS (25, 29). These surveys found that not all hospitals in the UK provide a PMHS, and that PMHS are provided in different ways (e.g., different hours of availability). Such differences in the provision of PMHS may affect the overall impact of this service to achieve its aim – to provide medicines-related support to patients following their discharge from secondary to primary care. Thus, the aim of this doctorate was to conduct high-quality research that examines the impact of PMHS on service users and healthcare organisations.

1.3 Research question for this doctoral research

The overarching research question to be addressed was: *What is the impact of National Health Service (NHS) patient medicines helpline services upon service users and healthcare organisations?*

The RE-AIM evaluation framework was used throughout the doctoral research in order to answer this question (30). Whereas most studies focus upon evaluating the effectiveness of an intervention to establish its impact, RE-AIM comprises five dimensions that are conceptualised as being important for evaluating the impact of interventions. These are: *Reach* (proportion and representativeness of the population receiving the intervention), *Effectiveness* (assessment of the positive and negative consequences of an intervention), *Adoption* (proportion and representativeness of settings that adopt an intervention), *Implementation* (extent to which an intervention is delivered as intended), and *Maintenance* (extent to which an intervention becomes a relatively stable, enduring part of the behavioural repertoire of an individual/organisation). RE-AIM was chosen since all five dimensions are relevant for examining PMHS.

1.4 Summary of chapters in this thesis

This thesis represents a PhD by publication, and is therefore structured by five papers that have either been published, or have been accepted for publication. The only chapters that do not contain papers are Chapter 1 (Structure of thesis), Chapter 2 (Overview of literature), Chapter 3 (Methodology), and Chapter 9 (General discussion). Chapters 4 to 8 contain the papers as published/accepted, in order of date of publication.

Chapter 2 provides an overview of the literature pertaining to the research topic at the start of the doctorate. Thus, *Chapter 2* provides a rationale for the doctoral research, and outlines its aims. A systematic literature review is not presented here, since two systematic literature reviews were conducted and published later during the doctoral research process (see *Chapters 5* and *6*).

Chapter 3 outlines the methodology used within this doctoral research. A rationale is presented for the theoretical framework used throughout this research (RE-AIM), and for the need to explore this topic using mixed methods. The ontological and epistemological positions used for this doctoral research are also presented.

Chapter 4 presents a cross-sectional survey study exploring current practice in the operation of PMHS in England. Since similar previously conducted studies were out-of-date (25, 29), the primary aim of this study was to establish a current baseline regarding the operation of PMHS that could be used to inform the development of subsequent studies. In this study, all five dimensions of the RE-AIM framework are used to examine PMHS (*Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance*). Specifically, this study aimed to (1) establish the percentage of NHS Trusts in England that provide a PMHS, and explore the reasons why some Trusts do not provide this service; 2) examine how PMHS are operated in England, by comparing how current practice meets with national standards for operating PMHS; 3) establish the average number of years that Trusts have operated PMHS, and the reasons why some Trusts stopped operating a helpline; 4) establish for whom PMHS are available, and the average number of enquiries received per week; and 5) establish pharmacy professionals' perceptions as to the benefits that their PMHS can have. The latter was considered important, since to date the perceived benefits of PMHS have been devised by a small working group of MI pharmacists for use within

guidelines aimed at increasing the provision of PMHS within the UK (31). This survey study was published in *BMC Health Services Research* in November 2018.

Chapter 5 presents a systematic review examining the literature pertaining to the effectiveness of MI services for patients and the general public. Therefore, this study examined PMHS by focussing upon the *Effectiveness* dimension of the RE-AIM framework. The aim of this study was to address the following research question: *What is the available evidence regarding the effectiveness of PMHS and medicines information services for the general public?* The findings of this systematic review are presented, and recommendations are made regarding improving clinical practice and future research endeavours. The published evidence found in this review are also useful in comparison to pharmacy professionals' perceived benefits of PMHS as established in the survey study (Chapter 4), in order to identify evidence gaps for future research. Thus, the findings of this review influenced the decision to primarily adopt a qualitative approach for the remainder of this PhD (see *Chapters 7* and *8*), since this was a noticeable gap within the literature. This systematic review was accepted for publication in the *International Journal of Pharmacy Practice* in July 2019.

Chapter 6 presents a systematic review examining the characteristics of users of PMHS, and the types of enquiries they make. Therefore, this study examined PMHS by focussing upon the *Reach* dimension of the RE-AIM framework. This was important, since the survey study (*Chapter 4*) found that the reach of PMHS could be improved, and a systematic review of extant literature would enable greater exploration of this. The aim of this study was to address the following research questions: *What are the characteristics of people who use PMHS? What are the characteristics of enquiries made to PMHS?* The findings of this systematic review are more generalisable to PMHS throughout the UK than individual service evaluations alone, and the findings are useful for establishing whether PMHS are under-used by any types of patients, and for also understanding patients' MI needs. This work has highlighted areas for the improvement of PMHS, and the chapter ends with relevant recommendations. This systematic review was accepted for publication in the *European Journal of Hospital Pharmacy* in October 2019.

Chapter 7 presents the findings of a qualitative study of pharmacy professionals' perceptions of providing a PMHS. The aim of this study was to address the following research question: *What are pharmacy professionals' experiences and perceptions of*

providing an NHS PMHS? In this study, all five dimensions of the RE-AIM framework are used to examine PMHS (*Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance*), from the perspectives of pharmacy professionals who provide a PMHS. This was important, since the survey study (*Chapter 4*) also examined all dimensions of the RE-AIM framework, albeit using survey methods. Therefore, this qualitative study provided PMHS providers the opportunity to describe the provision of PMHS in their own words, without the constraints of pre-specified survey questions and answer options. The chapter begins with a rationale for examining healthcare professionals' perceptions of healthcare services, and why this is important for PMHS. The findings from thirty-four interviews with pharmacy professionals are presented, along with a discussion as to the relevance of the findings. Based upon the findings, recommendations for improving PMHS are presented. This study was accepted for publication in *BMC Health Services Research* in April 2020.

Chapter 8 presents the findings of a qualitative study examining patients' and carers' experiences of using a PMHS. The aim of this study was to address the following research question: *What are patients' and carers' experiences of using an NHS PMHS?* In this study, the examination of PMHS primarily focussed upon the *Effectiveness* and *Implementation* dimensions of the RE-AIM framework. This is because service users are ideally placed to describe the effect that their PMHS had, and to use their experiences of contacting a PMHS to describe how it could be improved. The chapter begins with a rationale for examining service users' experiences of contacting PMHS. This was important since the systematic review examining the effectiveness of PMHS (*Chapter 5*) found that, to date, service users' experiences of PMHS had only been collected using survey methods. The findings from forty interviews with service users are presented, along with a discussion as to the relevance of the findings. Based upon the findings, recommendations for improving PMHS are presented. This study has been submitted to *BMJ Open.* Following peer review, it has recently been revised and resubmitted.

Chapter 9 presents the overall discussion and conclusions of this body of research. This includes the implications of the research for hospital-based pharmacy practice, and recommendations for improving PMHS and the provision of medicines-related support following discharge from secondary care. The chapter also includes recommendations for future research endeavours on this topic.

1.5 Chapter 1 summary

This introductory chapter presented a summary of the doctoral research and the chapters comprising this thesis. Next, an overview of relevant research literature pertaining to this doctorate is provided.

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Chapter 2: Overview of literature

2.1 Overview of Chapter 2

This chapter provides a rationale for the doctoral research, which examines the impact of National Health Service (NHS) patient medicines helpline services (PMHS). The chapter begins with a description of how medicines use is increasing, how patients have a need for medicines-related support following hospital discharge, and how managing patients' medicines-related issues after discharge can be burdensome for healthcare services. Next is a description of medicines information services as an intervention to provide medicines-related support to patients, with a focus upon PMHS. An overview of evidence pertaining to PMHS at the start of this doctoral research is then provided. Finally, this chapter ends with a description of the aims of this doctoral research.

2.2 Patients' need for support with medicines following discharge from secondary care

2.2.1 Medication use is increasing

Prescription and over-the-counter medications are both fundamental and commonplace components of healthcare worldwide, and are used to prevent, treat or manage illness and to improve patients' quality of life (1). Approximately half of people in both the United Kingdom and the United States of America take at least one prescribed medication on a regular basis (2, 3). Additionally, the use of medications is increasing. Between 2006 and 2016, the average number of prescriptions per head of the UK population increased from 14.8 to 20.0 per annum, and there has also been an increase of 46.8% in the total number of prescription items dispensed in the community (752.0 million in 2006, and 1,104.1 million in 2016) (4).

Polypharmacy is also growing in the general population. Polypharmacy is often defined as the concomitant use of five or more medicines (5). In a large Scottish cohort study, the proportion of adults prescribed five or more medications increased from 11.4% in 1995 to 20.8% in 2010 (6). Findings also suggest that polypharmacy is more common in the elderly population (6-8). In the UK, over half of

people over 65 years old take more than three prescribed medicines (9), and one in six people over the age of 65 take ten or more prescribed medicines (10). This is because as life expectancy increases, more chronic diseases are likely to co-occur over time, resulting in a growing need for pharmacological treatments for these diseases, and a higher number of prescriptions per individual (1). Research suggests that there are many risks associated with polypharmacy. Polypharmacy increases the risk of prescribing errors (11), adverse drug reactions (12), drug-drug interactions (6), suboptimal adherence (13), emergency department visits (14), unplanned hospital admissions (15, 16), and readmissions (17, 18). Polypharmacy also increases the likelihood that patients will lack knowledge or understanding of their medicines (19, 20). Medicines optimisation is an approach to safe and effective medicines use, with the aim of ensuring that people get the best possible outcomes from their medicines, using the best available evidence to guide decisions about care whilst also taking into account patients' needs, preferences and values (1, 21). Ensuring that a patient's medicines are optimised is important for increasing the likelihood that patients take their medicines as intended, and is especially useful regarding the management of polypharmacy in order to minimise the above risks (1, 22). Population projections produced by the Office for National Statistics suggest that the population of older people will significantly increase in the next two decades (23). This may indicate an increased need for interventions and services in the future to provide medicines-related support for this growing older population.

2.2.2 Patients' knowledge about medicines following discharge from hospital

Patients who have been discharged from secondary care healthcare settings have often experienced recent changes to their medicines regimen, including the addition of new medicines (22, 24-26). For example, during a hospital stay, approximately 60% of patients experience three or more changes to their medicines regimen (26). However, a growing body of evidence highlights that patients in the UK and internationally often lack knowledge of their medications following discharge from hospital (27-29). For example, Holloway et al. carried out an interview study with patients on five wards of a teaching hospital in Glasgow on the morning of their discharge (27). This study found that 60% of patients could not name at least one of their medicines, only 25% knew the prescribed dose of at least one of their medicines, and 30% did not know when or how to take at least one of their medicines.

Lacking knowledge of medicines may not be problematic, if patients have received clear written information about their medicines that they are able to understand and follow. However, evidence highlights that discharged hospital patients in the UK also often report not being able to recall receiving important information about their medications (27, 30-33). For example, results from the UK NHS annual Adult Inpatient Survey found that, between 2013 and 2017, 29-30% of patients (*n* range = 40000-55923) reported that they were not provided with completely clear written or printed information about their medicines. Additionally, 42-44% of patients (*n* range = 38384-52554) did not recall receiving any information from staff about side effects to look out for when they returned home (30). Dissatisfaction with information received about side effects accords with findings from research studies, such as a survey of 140 patients at an NHS Trust in the UK, conducted by Auyeung et al. (34). They found that 42% (*n* = 59) of participants were dissatisfied with information they received pertaining to the risks of developing side effects, and 40% (*n* = 56) were dissatisfied with information pertaining to what to do if a side effect occurs.

The above findings from the UK correspond with findings from international studies that also suggest that patients often lack medicines-related knowledge following discharge, particularly around side effects (35-39), and that patients often report not being able to recall receiving important medicines-related information (40-44). Qualitative and survey studies suggest that patients' lack of knowledge of their medicines following hospital discharge may be a consequence of healthcare professionals not always having the time to provide adequate discharge counselling (45-47).

2.2.3 Medicines-related problems following discharge from hospital

As well as often requiring information about medicines, a substantial proportion of patients who have been discharged from hospital will subsequently experience medicines-related problems, as evidenced by studies conducted in the UK (48-51) and internationally (52-54). As well as the potential to cause harm, medicines-related problems can cause patients to become non-adherent (55). Medicines-related problems are typically defined as events or circumstances pertaining to patients' medication that can potentially or actually reduce desired health outcomes (56). Medicines-related problems particularly pertain to adverse drug reactions (an unwanted or harmful reaction that occurs after the administration

of a drug or drugs), medication errors (mishaps that occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug), and adverse drug events (an injury resulting from the use of a drug, which includes adverse drug reactions and medication errors) (57, 58).

Two studies have been conducted that followed up cohorts of patients after being discharged from hospital within the UK in order to explore the percentages of patients that subsequently experienced medicines-related problems (48, 59). Marvin et al. (48) carried out a survey study that involved contacting patients three weeks after being discharged for a short-stay admission from a hospital in London. They found that 44% (*n* = 12) of the 27 patients in the study had experienced medicines-related problems, mainly around side effects and administration. Similarly, Mackridge et al. subsequently conducted a study that involved surveying ninety-nine patients by telephone approximately two weeks after discharge from one of six acute hospitals in the North-West of England (49, 59). They found that 35% (*n* = 35) of patients experienced medicines-related problems following discharge, mainly around adverse effects (63%, *n* = 22). Also, 59% (*n* = 59) of patients reported that they had sought information or help with their medicines following discharge, mostly from GPs. This shows how medicines-related problems following hospital discharge can have an impact upon other healthcare services, particularly primary care. However, both the study by Marvin et al. and the study by Mackridge et al. are limited by their small sample sizes, and the findings may not be generalisable since participants were recruited from one department at one NHS Trust (Marvin et al.) and one region within the UK (Marvin et al. and Mackridge et al.).

Whilst acknowledging the limitations of the studies by Marvin et al. and Mackridge et al., extrapolating from their findings, it seems plausible that approximately 36-44% of patients who are discharged from hospital in England may experience medicines-related problems.

2.2.4 Medicines-related harm following discharge from hospital

Studies have also been conducted to specifically examine patients' experiences of medicines-related harm following discharge from hospital. A recently conducted, multicentre prospective cohort study by Parekh et al., (60), published in 2018, examined medicines-related harm following hospital discharge. In this study, medicine-related harm was defined as an adverse drug reaction, or harm arising

from non-adherence. One thousand one-hundred and sixteen older adults were followed up for eight weeks after being discharged from one of five hospitals in Southern England. Assessment of harm was conducted by research pharmacists at sites, with all cases of medicines-related harm subsequently reviewed and confirmed or rejected by an independent group of experts (three senior Geriatricians and a senior researcher in clinical pharmacy). Therefore, a thorough approach was taken to establish incidents of medicines-related harm in this study. Using a combination of data collection methods (telephone interviews with participants, general practitioner records, and prospective review of hospital readmission records), Perekh et al. found that 37% (*n* = 413) of patients experienced medicines-related harm. Of these patients, 81% (*n* = 336) were considered to experience serious harm, and 52% (*n* = 214) of harms were potentially preventable. However, only 10% were classified as definitely preventable, and 41% were classified as possibly preventable. Four participants experienced fatal harm (e.g., one participant suffered a stroke associated with non-adherence to warfarin, and another patient died following a fall associated with lorazepam use; however, the latter was not described in enough detail establish how the fall was known to definitely be attributed to the use of lorazepam). Seventy-nine percent (*n* = 328) of participants who experienced medicines-related harm sought the help of healthcare professionals during the eight-week period, again showing how avoidable medicines-related issues following hospital discharge increase the demand upon other healthcare services.

Prior to the above study by Parekh et al., evidence pertaining to medicines-related harm following hospital discharge can be found in two systematic reviews (61, 62). Alqenae et al. found that, out of 35 studies, the median rate of adverse drug reactions for adults and elderly patients was 22%, and the median rate of adverse drug events was 18.8% (62). In the second systematic review, Parekh et al. found that, out of eight studies, the range of older adults experienced medicines-related harm (defined as experiencing an adverse drug reaction or an adverse drug event) following hospital discharge was 0.4% to 51.2% (61). An average was not conducted, due to the substantial methodological variation between the eight studies. Additionally, Parekh et al. found that between 35% and 59% of these incidences of medicines-related harm were considered to be avoidable (61). The findings combined illustrate that a substantial proportion of patients experience medicines-related harm following hospital discharge, particularly elderly patients, and many of these are considered avoidable. However, it is important to note that

the methodological quality of the studies in the systematic review by Parekh et al. were found to be moderate, and in five of the eight studies, there was a high risk of bias (61). Additionally, definitions of medicines-related harm differed across the included studies, and two did not report the definition that they used. Methodological quality of studies in the systematic review by Alqenae, was found to be mostly low and moderate (62). Such limitations may therefore affect the conclusions drawn from the above findings.

In 2017, the World Health Organisation launched a global patient safety challenge, which aimed to reduce severe and avoidable medicines-related harm by 50% over the next five years (63). Providing evidence-based healthcare interventions and services to patients in order to reduce medicines-related harm will be important in order to achieve this.

2.2.5 Medication errors during the hospital discharge process

Medication errors have been defined as a preventable event that may lead to inappropriate medication use or patient harm (64). Patients may experience medication errors during the hospital discharge process, including prescribing errors and incorrect or missing information on discharge summary documents (64-69). Two systematic reviews have recently been conducted that explore medication error rates following discharge from hospital (62, 70). In the first, published in 2016, Aldhwaihi et al. identified that dispensing error rates in hospital pharmacies were between 0.015% and 34% of dispensed items (70). This finding comes from fifteen studies, conducted in four countries (UK, United States of America, Brazil, and France), with six studies conducted within the UK. However, a limitation of this review is that the authors did not provide a breakdown of the error rates by country, and therefore the error rate for the studies conducted in the UK is unknown. Additionally, the authors did not conduct a grey literature search as part of the review, which may have excluded some relevant studies, and those studies that were included were not assessed for risk of bias. In the second systematic review, published in 2020, Alqenae et al. found the average medication error rate experienced by older adults following hospital discharge to be 53%, across five studies (62). However, Alqenae et al. did not report the denominator for this error rate, nor whether any of the five studies were conducted within the UK. They also did not provide a breakdown as to the error rates for different types of medication errors (e.g., prescribing, dispensing). Therefore, the reporting of findings from the

above systematic reviews does not provide any useful information pertaining to medication error rates within the UK.

A review of the prevalence of medication errors in the NHS in England was published in 2018 by Elliott et al. (64). This review identified four studies that examined medication error rates during the transition of care from hospital discharge (three with a retrospective design, one with a prospective design) (71-74). The prevalence of errors ranged from 0.2% to 81%, with the authors suggesting that the wide range possibly being a consequence of the broad definitions of medication error used in some of the studies. For example, the study that found an 81% error rate included prescribing errors, clerical errors, and errors regarding medicines stopped during admissions, and the definitions for each of these were considered to be broad (71). This highlights a limitation of the measurement of medication errors, since the use of different definitions and coding categories may influence study findings. From two studies, prescribing error rates ranged from 0.2% to 20.8% (*n* = 10/509; *n* = 54/259) (71, 73). From one study, the rate of potentially inappropriate medications was 26.7% (*n* = 52/195). In one study, 43% (*n* = 18/42) of patients were identified as having an error or discrepancy on their discharge summary. Three of the four studies examined the clinical relevance and severity of the medication errors. One study measured hospital readmission within thirty days of discharge. However, this study was limited by a small sample size, and of 42 participants, three experienced a hospital readmission. Of these three, two were found to have discrepancies in their discharge medication prescription. Although, a further limitation of this study is that no causal link can be made between the discrepancy and the readmission. In the two other studies that examined the clinical relevance and severity of errors, errors were assessed for their potential to cause harm to patients. In one study, out of 74 errors, 73% (*n* = 54) were potentially clinically relevant for patients, with 5.4% (*n* = 4) associated with potentially serious harm. In the other study, of 51 errors, one had the potential to cause temporary harm (0.02%).

Combined, the four studies in the review by Elliott et al. suggest that medication errors may be common, and some have the potential to cause harm to patients. However, Elliott et al. acknowledge a number of limitations with these studies, and study quality was variable (64). As noted, one study had a small sample size. Another study was conducted at a single centre, which was a specialist older people's unit of a hospital, thereby limiting its representativeness. In two other

studies, data were collected from just one hospital setting, which also limit their generalisability. Additionally, it was not clear that the methods of assessing errors was consistently applied in three of the four studies.

2.2.6 Medicines-related hospital readmissions

Until recently, NHS Trusts in England would experience restrictions on payments for readmission that occurred within 30 days of discharge from a previous (index) admission (75). Readmissions account for a significant amount of hospital expenditure, with a report from the National Audit Office in 2014 estimating that the annual cost of emergency readmissions within thirty days of discharge is £2.4 billion (76). Therefore, avoiding rehospitalisation is a priority for healthcare policy makers in the UK. Additionally, recent figures suggest that the numbers of readmissions within 30 days of discharge are increasing. Between 2013/14 and 2017/18, the rate of emergency readmissions increased from 12.4% to 13.7% (77). However, it is unknown how many of these were medicines-related. The following studies suggest that the proportion of emergency readmissions that are medicines-related may be substantial.

A recent systematic review of nineteen studies by El Morabet et al., published in 2018, found that rates of hospital readmissions due to medicines varied from 3% to 64% (median = 21%). Additionally, up to 87% (median 69%) of these medicines-related readmissions were deemed preventable (78). Two studies within this systematic review were conducted within the UK. One was a study conducted by Davies et al., which was published in 2010 (51). They found that approximately 20% of hospital readmissions within one year of the index admission were due to ADRs, with 57% judged to be avoidable (51). The second study was conducted by Witherington et al. and published in 2008. They found a 30-day hospital readmission rate of 38% that was attributable to medication in a sample of patients aged 75 years and older, with 61% considered to be preventable (65).

A recently-conducted, multicentre prospective cohort study, published in 2018, followed up 1280 older adults for eight weeks after being discharged from one of five hospitals in Southern England (60). The incidence of hospital readmission as a result of medicines-related harm was 78 per 1000 discharges. Additionally, the authors estimated that medicines-related harm in older adults costs the NHS £396 million annually, and £243 million of that is potentially preventable (£51.6 million

were classified as ‘definitely preventable’). Of these amounts, 90% were attributed to hospital readmissions (i.e., £356.4 million annually, with £218.7 million being potentially preventable). These findings are based upon the cost of NHS service use associated with each case of medicines-related harm. Where there was uncertainty, a more cautious approach was taken, suggesting that these amounts may be an underestimation.

2.3 Providing support to patients after discharge from secondary care

2.3.1 The provision of medicines information services

It is healthcare policy and procedure in the UK to ensure that patients’ medicines are managed optimally during the transition of care period, after they have been discharged from secondary care to primary care (1, 79, 80). Recommendations by the National Institute for Health and Care Excellence include sending a patient’s medicines discharge information to their nominated community pharmacy, and arranging for additional support for certain at risk groups (e.g., patients’ taking multiple medicines or with chronic or long-term conditions, and older people) such as pharmacist counselling, telephone follow-up, and GP or nurse home visits (1). A growing body of evidence highlights the potential effectiveness of community pharmacist involvement on 30-day hospital readmissions (e.g., hospital referral of patients to community pharmacies for medication reviews), as established in a systematic review and meta-analysis by Lussier et al. (81). However, this systematic review is limited by high heterogeneity (e.g., varied study designs and methods of analysis, and degree of pharmacist involvement in the interventions), and the inclusion of ten studies, six of which were rated as having a high or serious risk of bias. Research also suggests a potential benefit of timely electronic transfer of discharge documentation to community pharmacies (82, 83), and targeted counselling follow-up telephone calls to at risk patients conducted by hospital pharmacist (48, 84, 85).

However, for the above interventions, the onus is largely upon the healthcare professional to offer support to patients, particularly those deemed to be at-risk. Services are also available that enable the patient to seek help, should they feel they require it. This is important, since the above findings show that medicines-related issues following hospital discharge are not just experienced by at-risk patients (e.g., medication errors). World Health Organisation policy states that

offering information on medicines via Medicines Information centres, and providing public education about medicines, are two of twelve essential interventions to promote the rational use of medicines (86). Therefore, medicines information (MI) services have been established in many countries to support patients and the public who have questions regarding their medications (87-91).

2.3.2 NHS patient medicines helpline services

In the UK, a network of local and regional medicines information services, collectively known as UKMi, are based in the pharmacy departments of many NHS Trusts (92). The initial aim of these medicines information services was to provide medicines-related information and advice to healthcare staff regarding pharmacotherapy for their patients (93, 94). However, in response to evidence that patients often have unmet needs regarding their medications following hospital discharge, in 1992 the first patient medicines helpline service (PMHS) was established at an NHS Trust in the UK (95, 96). Since then, PMHS have become available at many NHS Trusts throughout the UK, to provide patients with a means of accessing medicines-related information and support following discharge (97). In 2014 a survey study was conducted that found that approximately 55% of hospital-based MI Centres provide a PMHS (97). Although there are ten regional MI Centres within England, these provide MI for healthcare professionals rather than patients. Therefore, PMHS are typically a local service, provided by NHS Trusts primarily for their own patients.

Providing a PMHS accords with healthcare policy recommendations regarding the importance of giving patients the opportunity to seek information about their care and to be involved in decisions about their care (98-101).

2.3.3 Medicines information services outside of the UK

The UK is unique, since other countries do not typically provide medicines helplines that are operated by a network of hospital pharmacy services specifically for their recently discharged patients to speak to a pharmacy professional about their medicines. In most countries, helplines are provided for the general public (also referred to in published literature as ‘consumers’, ‘public’, and ‘laypeople’) rather than patients of a specific hospital. Also, the services are typically provided from Drug Information Centers or Drug and Poison Information Centers, which are often

regional or national (91, 102-105). For example, in 2009 in the United States there were 89 Centers that served the general public, and these were typically situated in community hospitals, university hospitals, federal government hospitals, tertiary care facilities, and schools of pharmacy (106-108). Similarly, in the Scandinavian countries, Drug Information Centers are regional, and are affiliated with clinical pharmacology services at university hospitals (109-111). In the Netherlands there is a national drug information service (112). Additionally, consumers in some non-UK countries such as the United States may also have the option of acquiring medicines information from services which provide alternative communication methods to telephone helplines, such as online drug information services (113-115).

2.4 Overview of evidence pertaining to patient medicines helpline services at the start of this doctoral research

2.4.1 Proposed benefits of patient medicines helpline services

Although PMHS were initially set up to improve patients' knowledge and use of their medicines, guidelines for their implementation have suggested other benefits, for both service users and healthcare organisations (116). Potential advantages include improving patient adherence, reducing patient harm, highlighting medication errors so that healthcare staff can learn from them and put systems in place to reduce their future likelihood, reducing patients' avoidable use of other healthcare services (e.g., GP visits, Accident & Emergency visits, and hospital readmissions), and improving the patient experience of healthcare services (e.g., patient satisfaction with care) (117, 118). Table 2.1 provides an overview of the proposed benefits of PMHS by some of the main proponents of PMHS.

As seen in Table 1, PMHS are therefore perceived to be beneficial not only for service users, but also healthcare organisations in terms of learning from patient experiences (e.g., using information about errors to improve healthcare services) and reducing the burden on other services. However, further research is needed to ascertain whether these proposed benefits can be evidenced. Additionally, the proposed benefits were developed by a small working group of MI pharmacists, and therefore, there may be other perceived benefits of PMHS that are not included within Table 2.1.

Table 2.1. Summary of the potential benefits of providing a patient medicines helpline service, proposed by Wills et al. (116)

Benefits for patients	Benefits for NHS Trust and other healthcare services
Provides support during transition of care, when patients can experience information gaps.	Reduced readmission rates (i.e., improvement in Trust targets; avoiding penalties for emergency readmissions).
Ability to access professional support from home.	Provides a back-up to discharge counselling.
Patients may avoid harm.	Assurance to staff that patients have access to professional contact once home.
Medicines may be optimised, so that patients obtain the best possible outcomes from their medicines.	Patients' opinion of Trust may improve (i.e., satisfaction ratings).
Interactions are avoided.	Helpline is positive message from Trust to local media.
Provides personalised patient advice.	Early warning for Trust about areas of risk.
Patients have a right to information about their treatments.	Prevention of complains and litigation.
	Picks up critical incidents and errors (i.e., ability to learn from adverse patient experiences so that poor practice can be improved).
	Service is inexpensive to run, and meets needs of a large population.
	Engaging the local community is a key aspect of a Foundation Trust's role.
	Putting patients' needs at the heart of services (a core NHS value).
	May reduce burden on primary care.
	May reduce attendances to Accident & Emergency departments.

Abbreviations: NHS = National Health Service.

2.4.2 Types of enquiries answered by patient medicines helpline services

In their examination of sixty-nine PMHS in the UK, Raynor et al. found that the most common enquiries related to adverse effects (41%), dosage and administration (27%), and interactions (21%) (119). However, this study was published in 2000 (year of data collection unknown) and therefore may not be representative of the types of calls received to PMHS currently. More recently, in their 12-month review of calls received to their helpline, Bramley et al. found that the most common reason for calling was a lack of appropriate information on the discharge letter (24%), followed by drug interactions with other drugs or medical conditions (11%), adverse drug reactions (10%), supply (8%), general information about side effects (7%), error (6%) and advice about medicines changes (6%) (97). However, these findings come from 413 enquiries received to only one helpline and may not be generalisable. Additionally, collecting data pertaining to the type of enquiries received does not provide evidence as to the quality of the information provided, nor whether the enquiries received were even able to be dealt with by the PMHS. For example, in the study by Raynor et al., adverse effects comprised 41% of enquiries. It may be that PMHS are able to provide information pertaining to potential side effects to look out for, yet their role may be limited if a patient contacts the service and is actually experiencing side effects. Therefore, research is needed to establish not only the types of enquiries received to PMHS, but whether the service was even able to help the patient.

Furthermore, in the Bramley et al. study (97), most enquiries received to their PMHS pertained to a lack of appropriate information on the discharge letter (24%). Thus, by providing additional appropriate information to patients' discharge letters, the number of enquiries to their service would reduce by 24%. This suggests that providing a PMHS may be a mechanism for establishing ways to improve patients' care earlier in their care pathway, therefore reducing their need to contact the hospital for help after being discharged. Relatedly, a study by Marvin et all found that, of 500 calls to their PMHS, 34% pertained to medication errors (120). This suggests that if mechanisms were put in place to reduce the number of medication errors that occur, the number of calls to PMHS may reduce. Research is needed to establish whether this is the case. This is important, since earlier in the chapter the evidence pertaining to medicines-related errors during the transfer from secondary to primary care in the UK suggested that such errors may be fairly common (64).

Earlier in the chapter, it was also noted that the proportion of medicines-related harm following hospital discharge may also be substantial (i.e., approximately 37% in a cohort of 1116 older adults by Parekh et al.; (60)). Relatedly, Marvin et al. (2011) found that, of 500 calls to their PMHS, 48% were concerned with harm or judged to have the potential for harm had professional information not been available. One percent of calls were considered to pertain to serious harm, defined as requiring intervention and referral. These findings suggest that PMHS have the potential to be of benefit for preventing harm (albeit not serious harm in most cases) to approximately 37% of older patients who have been discharged from hospital. However, this is dependent upon patients being aware that they have an issue with their medicines, being aware that PMHS exist, and choosing to use this service. Therefore, the percentage of older patients who may avoid medicines-related harm through contacting a PMHS would likely be much lower. Additionally, the finding by Marvin et al. was established from data collected at one site, and where the provider of the service also coded the enquiries in terms of potential for harm. Therefore, measurement bias may have occurred (i.e., coding the enquiries in such a way to make the service seem more useful than it actually is). The study also does not provide detail as to exactly how the PMHS was able to prevent harm to patients. Further research is needed to establish this, and establish the generalisability of these findings, through research that is conducted independently of the sites being examined.

2.4.3 Prevalence of patient medicines helpline services

Establishing the prevalence of NHS PMHS in the UK is useful to gauge the uptake of this service by pharmacy teams from the time that the first helpline was set up approximately 28 years ago. At the start of this doctoral research, four studies had been published that described the prevalence of PMHS (97, 121-123). However, these studies measured the number of helplines in slightly different ways, rendering them difficult to compare to one another in order to establish change in the prevalence of helplines over time (see Table 2.2).

Table 2.2. Differences in the measurement and reporting of the prevalence of NHS patient medicines helpline services in four studies

Study	Year Published	Year of Data Collection	Unit of Measurement	Geographical Coverage of Study	Participants	Sample Size	Prevalence of PMHS
Sexton et al. (121)	2000	1999	Acute NHS Trusts	UK	Pharmacist at the Trust, chosen by the Trust's Chief Pharmacist	163/222 Acute NHS Trusts	NR, although 44% of the sample advertised a PMHS to patients
Healthcare Commission (122)	2007	2005-6	Acute and Specialist NHS Trusts	England	NR	173/173 Acute and Specialist NHS Trusts	64%
Healthcare Commission (123)	2007	2005	Mental Health NHS Trusts	England and Wales	NR	42/83 Mental Health NHS Trusts	31%
Bramley et al. (97)	2014	Not reported	MI Centres	UK	MI Managers	184/184 MI Centres	55%

Abbreviations: MI = medicines information; NHS = National Health Service; NR = not reported; PMHS = patient medicines helpline service; UK = United Kingdom

Overall, the findings suggest that approximately half of NHS Trusts may provide a PMHS. The most recent study was published in 2014 and was conducted by Bramley et al. (97). They found that PMHS were provided by 102 out of 184 UK Medicines Information (MI) teams (55%). However, by only surveying MI teams, Bramley et al. may not have included all NHS secondary care PMHS in the UK. For example, Raynor et al. (119) found that, in 33% of hospitals, the medicines helpline telephone was located in the dispensary. If any of these hospitals did not have an MI team, then it may be possible that they would not have been identified in the survey by Bramley et al. Furthermore, since the study by Bramley et al. was conducted, guidelines and national standards have been published to provide guidance to hospital pharmacy and MI teams in the UK in order to set up and operate their own PMHS (116, 118). It therefore seems plausible that the finding by Bramley et al. is an underestimation of the number of medicines helplines currently in operation in the UK.

The findings by Bramley et al. are also difficult to compare to the findings by the Healthcare Commission, published in 2007, which measured the number of *NHS Trusts* that operated a helpline (122, 123). Some MI teams provide their services to more than one NHS Trust (i.e., via a service level agreement), since some Trusts do not have their own MI team. Additionally, some NHS Trusts have more than one MI team, such as one at each hospital within the Trust. These factors may account for why the proportion of PMHS found by Bramley et al. is lower than that found by the Healthcare Commission, which was published seven years earlier. Therefore, it may be beneficial to establish the current provision of PMHS, using NHS Trusts as the unit of measurement, thus generating data that can be compared to the findings of the Healthcare Commission approximately ten years ago. Additionally, individuals become patients of NHS Trusts rather than MI Centres, and so the provision of PMHS at NHS Trusts would be more important to patients, rather than the provision of PMHS at MI Centres.

2.4.4 The operation of patient medicines helpline services

Surveys examining the operation of medicines helplines in the UK describe, for example, the number of calls received per week, the hours and days of availability of the service, the methods of accessing the service, the methods of advertising the service, the occupation/qualifications of staff who deal with enquiries, the use of guidelines/procedures, and the use of auditing/monitoring procedures (97,

119). At the start of this doctoral research, two studies had been published that examined the operation of PMHS, and both used cross-sectional surveys completed by healthcare professionals (97, 119). However, the most recent was published in 2014 (year of data collection not reported) (97), and the first was published in 2000 (119). Therefore, the operation of PMHS in the UK at the start of this doctoral research was unknown. Additionally, since 2014, national standards have been published and endorsed by the UKMI to provide guidance as to what constitutes acceptable and commendable provision of PMHS (118). Therefore, it would also be beneficial to explore whether providers of PMHS are specifically meeting these standards.

2.5 The aim of this doctoral research

The NHS is committed to providing evidence-based patient care (124). However, so far only a paucity of descriptive data exists to attempt to answer whether PMHS are effective at delivering what their proponents suggest are benefits of operating such a helpline (117, 118). Studies examining PMHS have primarily been service evaluations where the providers of PMHS have evaluated their own services, which may have biased their findings (e.g., selection and measurement bias). Additionally, many findings are likely to be out-of-date (e.g., those examining the provision and operation of PMHS).

The aim of this doctoral research was therefore to examine the current impact of NHS PMHS. As described in more detail in the following chapter, the impact of PMHS was examined throughout this doctoral research using the RE-AIM evaluation framework (125). RE-AIM conceptualises 'impact' as being the product of an intervention's reach, effectiveness, adoption, implementation, and maintenance (125).

Due to the lack of high-quality research to date, much of this doctoral research constituted providing the foundations for future research on this topic, and establishing gaps in the evidence-base. Therefore, a survey was conducted to establish the percentage of NHS Trusts that provide a PMHS, and to explore current practice in the operation of PMHS. Also, two systematic reviews were conducted; one examining the evidence regarding the effectiveness of MI services for patients and the general public, and a second examining the characteristics of PMHS enquirers and the enquiries they make. Based upon this initial work, the final two

studies were designed to address gaps in the literature. Both are qualitative studies; one examined pharmacy professionals' perceptions of providing a PMHS, the other examined patients/carers experiences of using a PMHS.

Throughout this doctoral research, the findings of each study have resulted in the development of recommendations for improving current practice regarding the provision of PMHS (summarised in Chapter 9: General discussion). Adding to the limited evidence that was available at the start of this doctoral research has helped to establish whether PMHS achieve what they aim to achieve (i.e., provide medicines-related support to patients and carers during the transition from secondary to primary care), and whether the provision of PMHS may be improved to ensure that the needs of service users are being met. Additionally, proponents of PMHS suggest that PMHS may also function to be of benefit to healthcare organisations (e.g., provide NHS Trusts the opportunity to learn from errors identified via helpline enquiries, and reduce the burden upon other healthcare services such as GPs). Thus, this doctoral research provided the opportunity to also explore whether PMHS have an impact upon healthcare organisations.

2.6 Chapter 2 summary

This chapter introduced the topic for this doctoral research, including why such research is needed. Patients and carers have a need for medicines-related support following discharge from secondary to primary care. Patient medicines helpline services have been established at some NHS Trusts to enable patients and carers to seek support with their medicines. However, little high-quality research has been conducted to examine this service. Therefore, the aim of this research was to conduct high-quality research to examine the impact of PMHS. The RE-AIM evaluation framework was used throughout this research, which conceptualises that the impact of an intervention is the product of its reach, effectiveness, adoption, implementation, and maintenance.

The following chapter explores the methodological approach used for this research, and describes the RE-AIM framework in further detail.

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Chapter 3: Methodology

3.1 Overview of Chapter 3

Chapter 3 outlines the methodology used in this doctoral research. The chapter begins with the overarching research question for this doctoral research, and then describes the research approach used to answer this question – mixed methods, using the RE-AIM (*Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance*) evaluation framework. Next, pragmatism is described as the main philosophical approach that has been endorsed by mixed methods researchers, and the reasons why it was chosen for this doctoral research.

3.2 Research question for this doctoral research

As stated in Chapter 1, the overarching question that this doctoral research addressed is: *What is the impact of National Health Service (NHS) patient medicines helpline services upon service users and healthcare organisations?*

3.3 Defining 'patient medicines helpline services'

Although some studies have been conducted to examine PMHS, to date a definition of PMHS does not exist. For this doctoral research, PMHS will be defined in the following way.

- A service providing medicines information and advice, and not general clinical information and advice;
- A service for patients and/or carers of patients who received care from the NHS Trust within the UK that provides the PMHS, and not for a specific subset of patients and/or their carers; and
- A service involving distance communication, via any means, between the service user and service provider, instigated by the service user.

At the start of this doctoral research, this definition was reviewed by four pharmacists with backgrounds in Medicines Information, and no changes were considered necessary.

3.4 Methodology of this doctoral research

3.4.1 Using the RE-AIM evaluation framework to examine the impact of patient medicines helpline services

The aim of this research is to examine the impact of PMHS. To examine the impact of PMHS, the RE-AIM evaluation framework will be used throughout this doctoral research. The RE-AIM framework was first published in 1999 by Glasgow et al., and aims to identify the different ways that an intervention has impact (1). The framework developed out of a need for improved research and reporting of findings pertaining to the implementation and validity of health interventions, and to facilitate the translation of research findings so that effective interventions are more widely adopted. However, Glasgow et al. acknowledge that the way in which RE-AIM is applied can vary, and that the framework has and will continue to evolve to meet the needs of its users (2). Being twenty years old, RE-AIM is a well-established framework for evaluating the impact of health interventions (3, 4).

RE-AIM is based upon the work of Abrams et al. (5) who defined the impact of an intervention as the product of a programme's *reach* (the percentage of the population receiving the intervention) and its *efficacy* (assessment of both positive and negative consequences of an intervention). Glasgow et al. (1) expand on this conceptualisation of the impact of an intervention to develop RE-AIM, by adding three dimensions that apply to the settings in which research is conducted. The three other dimensions are *Adoption* (the absolute number, proportion, and representativeness of settings and people who are willing to initiate a program, and why), *Implementation* (the extent to which an intervention is delivered as intended, the time and cost of the intervention, and adaptations made to the intervention), and *Maintenance* (the extent to which an intervention becomes a relatively stable, enduring part of the behavioural repertoire of an individual/organisation; the long-term effects of a service or intervention on its users after it has been completed). Glasgow et al. also expanded the definition of *Reach* (the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not). Additionally, Glasgow et al. suggest that 'efficacy' could be replaced with 'effectiveness', depending on the stage of research and/or the intervention being investigated, in order to assess its impact in terms of actual changes in real-life conditions (6). The definition of *Efficacy*/*Effectiveness* was also expanded (the impact of an intervention

on important individual outcomes, including potential negative effects, and broader impact including quality of life and economic outcomes; and variability across subgroups).

Glasgow et al. emphasise the importance of focusing on all five dimensions of the framework in order to fully evaluate the impact of an intervention, and that this is more likely to result in research findings being translated into practice (2, 4). The 'RE' dimensions are primarily concerned with the impact on the individual (e.g., is an intervention beneficial for the people receiving it, and are all individuals who can benefit from the intervention receiving it?). The 'AIM' dimensions are primarily concerned with the impact of an intervention at the level of the intervention setting (e.g., are sites which could offer the intervention, actually offering it? If a site offers the intervention, is it being offered as intended? And if so, is this stable over time?). Glasgow et al. suggest that the 'AIM' dimensions are less often studied but are equally important factors in determining an intervention's impact (4, 7).

Although originally the focus of RE-AIM was upon assessing the impact of an intervention using quantitative data, the framework has been expanded to emphasise the importance of qualitative data to understand the framework's different dimensions (2, 4). For example, Kessler et al. (2) propose that the use of qualitative data are important for understanding the reasons for not adopting the intervention (adoption) and for non-participation in the intervention (reach), and for further exploring the outcomes of an intervention (efficacy/effectiveness). The RE-AIM framework therefore accords with the mixed methods approach, whereby qualitative findings can elucidate quantitative findings, by generating knowledge that cannot be generated via quantitative methods alone. The use of mixed methods are encouraged by the developers of RE-AIM (2).

Other frameworks have been developed for the purpose of evaluating healthcare interventions and services, such as APEASE (comprising of six criteria: affordability, practicability, effectiveness, acceptability, side effects/safety, and equity; (8)) and the Medical Research Council (MRC) guidance for developing and evaluating complex interventions (9). PMHS are not a complex intervention, and so the MRC guidance is not appropriate to evaluate this service. The APEASE criteria is a relatively recent framework, first published in 2014 (8). Therefore, at the time of choosing a framework at the start of this doctoral research, the APEASE criteria had not been widely used (a search for literature at the time showed that only a few

studies had used it, primarily to develop interventions rather than evaluate them), whereas the RE-AIM framework had been widely used, and in a variety of contexts (4). Relatedly, the APEASE criteria did not appear to be evidence-based; its developers did not provide detail as to how the criteria were developed. However, the criteria appear to be similar to other previously developed frameworks for evaluating the quality of healthcare services and interventions, such as those by Donabedian, Maxwell, and Higginson (all four frameworks include the dimensions *effectiveness*, *acceptability*, and *equity*, and three of the four also include *accessibility*) (10-12). Additionally, the RE-AIM is the only framework that purports to examine the *impact* of interventions and services. The APEASE criteria, and the frameworks proposed by Donabedian, Maxwell, and Higginson are described as examining the *quality* of healthcare interventions and services. Therefore, the RE-AIM framework seemed more of an appropriate fit for answering the overarching research question for this PhD (i.e., Examining the *impact* of NHS PMHS on service users and healthcare organisations). Despite this, it is important to acknowledge that the RE-AIM conceptualisation of *impact* is not absolute. *Impact* is a construct, and it has been conceptualised by the developers of RE-AIM as consisting of an intervention's reach, effectiveness, adoption, impact and maintenance, by a small group of academics (1).

Nevertheless, the RE-AIM framework is a useful tool for examining PMHS, since all five of the framework's dimensions are relevant. Therefore, the knowledge generated from this doctoral research will be enhanced, rather than solely focusing upon, for example, the examination of the effectiveness of PMHS. PMHS could potentially be adopted by all NHS Trusts with the aim of being available for all of a Trust's patients (*RE-AIM Adoption* and *Reach*, respectively). Additionally, national standards for setting up and operating a PMHS in the UK have recently been developed, and are endorsed by the Royal Pharmaceutical Society [46]. This provides the opportunity to evaluate the extent that current practice in the provision of PMHS meets these standards (*RE-AIM Implementation*). The longevity of PMHS could be examined by establishing for how long PMHS have been provided, and reasons for their continuation or their closure at certain sites (*RE-AIM Maintenance*). Additionally, the longer-term impact that the helpline advice may have upon service users could also be examined, such as sustained improved use of medicines (*RE-AIM Maintenance*). However, since each of the five RE-AIM dimensions comprise sub-elements, it may not be possible to examine them all within this doctoral research due to time and resource constraints. Therefore, any aspects of the

framework that were not used to examine the impact of PMHS will be noted within the Discussion chapter of this thesis.

3.4.2 Mixed methods approach

As described above, examining the impact of an intervention using the RE-AIM evaluation framework is likely to include both quantitative and qualitative approaches. Thus, a mixed methods approach was chosen for this doctoral research. *Mixed methods research* refers to "research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of study" (Pg4, (13); see also Johnson, Onwuegbuzie & Turner, (14)). To date, the use of mixed methods research in pharmacy practice has been relatively limited (15). Because the investigation of MI services is a relatively new area of research for pharmacy practice, mixed methods research would be useful to provide both breadth and depth for exploring this topic. Additionally, a main initial aim was to explore service users' experiences of using PMHS, for which qualitative methods are appropriate. However, another aim was to generate background data such as establishing how many NHS Trusts provide a PMHS, and whether the extant helplines meet national standards for PMHS provision (16), for which quantitative methods are appropriate. Both are important knowledge gaps, as detailed in Chapter 2. Therefore, employing a mixed methods approach was considered appropriate. What follows is an overview of mixed methods research.

During the last two decades there have been increasing calls for mixing the contrasting paradigms of quantitative and qualitative research, rather than choosing one or the other methodological approach (17-20). This is because both quantitative and qualitative approaches have strengths and limitations, and neither one is considered a best overall method (14, 19, 21). Quantitative research produces data that are numerical, enabling comparisons to be made between participants and across studies, and the ability to test causal hypotheses using experimental designs (the hypothetico-deductive method). Qualitative approaches produce in-depth, textured data, whereby the personal meanings and lived-experiences of individuals are prioritised. Qualitative research is also useful for the generation of hypotheses/theory. Compared to quantitative research, which takes a nomothetic approach (i.e., relating to the discovery of general rules/laws), the idiographic approach of qualitative research places greater importance upon context, and

individuals' insights, understandings, and meanings of their lived experiences (22). The combination of quantitative and qualitative methods is likely to result in what Turner and colleagues describe as complementary strengths and non-overlapping weaknesses, with the product being superior to that of single method studies or projects (19, 23). Thus, mixed methods research has been established as a third methodological paradigm (14, 18, 19, 24).

When both qualitative and quantitative data are collected within a study or series of related studies, results may be enriched in ways that one form of data alone would not enable. For example, with mixed methods research it becomes possible to generalise results from a sample to a population, and to also gain a deeper understanding of individuals' motives, assumptions, beliefs, and other relevant cognitions regarding a phenomenon of interest (25). As well as potentially providing more detailed answers to research questions, mixed methods research can identify new research questions, suggest changes to future research designs, and enhance theory development and practice (19, 26).

The mixed methods approach has become increasingly popular within healthcare research. For example, the incidence of mixed methods studies commissioned by the Department of Health Research & Development programme between 1994 to 2004 increased from 17% to 30% (27). This increased use of mixed methods research in health services research may be motivated by recognition of the complex factors that influence health, illness, and healthcare, alongside a move towards a more patient-centred approach within both healthcare and research (28). Quantitative methods are useful within healthcare because of their generalisability of findings, such as conducting clinical trials that examine the efficacy of healthcare interventions and to establish whether an intervention works for a particular health condition or for a particular population (9). However, qualitative research can elucidate why some types of intervention work, and also why it may not work for everybody, by asking patients themselves about their experiences. Thus, qualitative research can be important in understanding *why* interventions are effective or not, and *how* they can be improved (29, 30).

3.5 Ontology and epistemology

3.5.1 Ontology and epistemology of this doctoral research

Although mixed methods research has become popular, particularly within applied fields such as healthcare and health services research, its corresponding philosophical paradigm has often been ignored (31). However, recently, pragmatism has been identified as an appropriate philosophical paradigm for conducting mixed methods research (15, 18-20, 24, 26, 28, 32-34). With its focus upon the consequences and usefulness of research findings, pragmatism was considered an appropriate approach to explore the impact of PMHS, in order to develop recommendations for service improvement for the benefit of users and providers of PMHS. Additionally, the use of the RE-AIM framework, with its emphasis upon the importance of translating research findings into practice, also accords with the principles of pragmatism (18, 19, 24, 35). Thus, the epistemological position of pragmatism was adopted for this doctoral research. What follows is an overview of different ontological and epistemological approaches, including pragmatism and its application within health services research.

3.5.2 Positivist/empiricist versus interpretivist/constructivist approaches

Quantitative research is typically driven by realist ontology (i.e., reality is independent of human minds), with positivist and empiricist epistemologies (i.e., reality is what can be scientifically verified, and knowledge is based on experiences derived from the senses, respectively). This paradigm posits that there is a stable reality independent of the individual, and that this reality is capable of being studied and known. Additionally, according to this paradigm, emotional, subjective, or political perspectives should not influence empirical scientific enquiry. Quantitative research therefore takes an objective, value-free stance towards a phenomenon being studied, using methods and measures that are fully independent from the researcher. Qualitative research, on the other hand, is typically driven by relativist ontology (i.e., reality is a subjective experience dependent upon human minds), with constructivist and interpretivist epistemologies (i.e., knowledge is constructed based upon our understanding of the world, and that scientific investigations are shaped by the interpretations of the investigators, respectively). Here, reality is regarded as a construction within each individual's mind, whereby multiple realities may exist simultaneously. Each person's construction cannot be verified, since there is no

reality against which to verify them. Qualitative research takes the position that an objective account therefore cannot be achieved; there is only subjectivity, since each individual holds existing assumptions, beliefs, and attitudes about a phenomenon of interest (36). For qualitative researchers, the development of knowledge is seen as contextual, embedded in values and cultures, including the research process itself (37). The aim of qualitative research is to explore and understand a phenomenon of interest, rather than testing theoretically-driven hypotheses about it (36, 37).

3.5.3 Pragmatism

Pragmatism largely abandons the debate over positivist versus interpretivist/constructivist approaches to inquiry. This is because ultimately the two approaches share the same goal of seeking to generate knowledge that corresponds with reality, irrespective of whether reality is singular or multiple (19, 35, 38). Instead, pragmatism orients itself toward choosing appropriate methods for solving practical problems with an emphasis upon the consequences and usefulness of research, i.e. research leading to action, such as the translation of findings into recommendations for practice that are then implemented (18, 19, 24, 35). Pragmatism therefore does not abandon the epistemological differences between qualitative and quantitative approaches but acknowledges that both are important for producing different types of knowledge (19, 24). Thus, approaching research from either a quantitative or a qualitative approach would likely be limited for answering all types of research questions. In this sense, the dichotomy between quantitative and qualitative research is unnecessary, since answering research questions usefully and thoroughly may require both methodologies in order to provide a more complete picture (19, 24).

Philosophically, pragmatism accepts that there are both singular and multiple realities that are open to empirical enquiry (24). For example, reality could be seen as layered, whereby there may be a single real world, and yet all individuals have their own interpretations of it (18). With pragmatism, there is a commitment to uncertainty – that knowledge produced is relative and not absolute (32). Pragmatism is considered by many mixed methods researchers to be preferable to other potential philosophical approaches to mixed methods research, such as critical realism (39, 40). Critical realism is a post-positivist philosophy of science. Ontologically, as with pragmatism, critical realism posits that there is an

absolute reality which is independent of human action, but that it cannot be observed objectively. Reality is conceived of as stratified, comprising what we *actually* experience, what we *can* experience but do not, and underlying causal mechanisms which can be hypothesised and are only indirectly observable through their effects. The aim of knowledge generation is to understand these causal mechanisms. Critical realism recognises that each person's perceptions of a phenomenon are unique, since they are based upon individual and shared experiences and are governed by context (e.g., social structures). In this sense, critical realism accords with epistemological relativism since the generation of knowledge is viewed as historically emergent and fallible (41). Therefore, there are several similarities between pragmatism and critical realism (i.e., that objectivity and subjectivity can co-exist, that knowledge generation is context-dependent and fallible, and that research should be value-oriented). However, pragmatism places less emphasis upon ontological and epistemological assumptions for conducting research compared to critical realism, thereby being less restrictive in terms of how research can be conducted (26, 42, 43).

With pragmatism, the research question is of primary importance, rather than the method or the philosophical paradigm underlying the method (18, 19, 44). Pragmatists hold that research should therefore not aim to accurately represent or 'mirror' reality, but to produce findings that have utility (35). For Morgan, the pragmatic approach abandons the top-down privileging of ontological assumptions, whereby ontology influences epistemology, which in turn influences methodology and the methods used within research endeavours. Instead, for Morgan, methodology should be the primary focus of research, and it should be the methodology that connects epistemology to the actual methods used, rather than the methods being dictated by the epistemology (18). This focus upon methodology helps to ensure that research is conducted thoughtfully and to a high standard (18). Therefore, within pragmatism, methodology is chosen based upon its usefulness for answering the research question, rather than based upon a pre-existing commitment to the philosophical underpinnings of a particular paradigm. However, for pragmatists, not all research questions are important, just as not all research methods are appropriate (18). With pragmatism, there is an emphasis upon producing knowledge in the pursuit of desired ends, and often, those ends involve ethical and moral issues (19). The focus of pragmatism regarding the usefulness and consequences of research accords with health research which aims to produce findings that are of benefit to service users in order to alleviate suffering and

improve quality of life (24, 33, 45). Pragmatism therefore accords with the aim of this doctoral research, which is to explore the impact of PMHS upon service users and healthcare organisations, and if relevant, suggest recommendations for the improvement of this service in order to enhance its impact.

3.6 Chapter 3 summary

Chapter 3 has presented the theoretical framework underpinning this doctoral research. The epistemological position of pragmatism has been adopted for this research, which comprises mixed methods. This chapter also described how and why the RE-AIM framework will be used throughout this doctoral research. RE-AIM comprises five dimensions considered necessary to examine the impact of interventions and services, and was chosen since all five dimensions are particularly useful for evaluating PMHS.

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Chapter 4: Operating a patient medicines helpline. A survey study exploring current practice in England using the RE-AIM evaluation framework

4.1 Overview of Chapter 4

This chapter presents the first study of this doctoral research. Previous findings show that PMHS are not provided by all NHS Trusts (1, 2), and that the way PMHS are operated is variable, particularly pertaining to hours/days of availability and promotional methods (3, 4). However, these findings are likely to be out-of-date. Although a study by Bramley et al. examined the provision of PMHS in a study that was published in 2014, the year of data collection was not reported (4). Additionally, they examined the percentage of medicines information centres that provide a PMHS, rather than the percentage of NHS Trusts that provide this service. The most recent studies to examine the percentage of NHS Trusts that provide a PMHS were published in 2007 and conducted by the Healthcare Commission (1, 2). It was therefore unknown how many NHS Trusts currently provide a PMHS, and there was a gap in the literature for establishing this. Knowing the prevalence of PMHS in the UK is useful to gauge the uptake of this service by pharmacy teams from the time that the first helpline was set up approximately 28 years ago. Relatedly, although the most recent study to examine the way that PMHS are operated was published in 2014 (again, by Bramley et al., where the year of data collection was not reported (4)), a more thorough examination was published in 2000. Therefore, it was also unknown how PMHS are currently being operated.

The aim of this cross-sectional survey study was to provide a foundation for further work on this topic, by establishing some key background information pertaining to PMHS. Namely, the number of PMHS being operated within England and the percentage of NHS Trusts that currently provide one (aspects of *RE-AIM Adoption*), and the ways that this service is being operated (aspects of *RE-AIM Implementation*). The other three aspects of the framework were also useful to explore, in order to provide background data pertaining to the use of PMHS (an aspect of *RE-AIM Reach*), pharmacy professionals' perceptions as to their

effectiveness (an aspect of *RE-AIM Effectiveness*), and the length of time PMHS have been in operation (an aspect of *RE-AIM Maintenance*).

A further aim of this study was to locate sites that were interested in taking part in further studies pertaining to PMHS. This enabled potential recruitment sites to be established for subsequent PhD studies (i.e., Studies 4 and 5).

This study forms part of a sequential mixed methods design, along with Study 4 (*Pharmacy professionals' experiences and perceptions of providing NHS patient medicines helpline services: A qualitative study*, described below). However, Study 1 alone is an example of a *quantitatively-driven mixed methods design* (5). Although the primary aim was to derive numerical data pertaining to the current provision and operation of PMHS in England, some qualitative data were also collected. For NHS Trusts that did not provide a PMHS, and for NHS Trusts that provided a PMHS in the past that subsequently closed, participants were able to write their perceived reason/s for this.

This study was published in BMC Health services Research in 2018. Therefore, the published article is presented. Following the article is a brief summary of the study's findings, and a description of how the study fits within the wider context of the PhD.

4.2 Statement of authorship

This declaration concerns the article entitled:			
Operating a patient medicines helpline. A survey study exploring current practice in England using the RE-AIM evaluation framework			
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** √			
Publication details (reference)	Williams M, Jordan A, Scott J, Jones MD. Operating a patient medicines helpline: a survey study exploring current practice in England using the RE-AIM evaluation framework. BMC health services research. 2018 Dec 1;18(1):868.		
Copyright status (tick the appropriate statement) I hold the copyright for this material √ ☐ Copyright is retained by the publisher, but I have been given permission to replicate the material here ☐			
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… *Formulation of ideas*: I formulated the ideas for this study (90%), with support from my supervisory team (10%). *Design of methodology*: I designed the methodology for this study (90%), with support from my supervisory team (10%). *Experimental work*: I carried out the study (i.e., collected and analysed the data) (100%). *Presentation of data in journal format*: I wrote the study for publication (85%), with support from my supervisory team (15%).		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	05/03/2020

4.3 Published article

The published article represents pages 52 to 64 of this thesis (13 pages).

Table 1 in the published article represents Table 4.1 of this thesis.
Table 2 in the published article represents Table 4.2 of this thesis.
Table 3 in the published article represents Table 4.3 of this thesis.
Table 4 in the published article represents Table 4.4 of this thesis.
Table 5 in the published article represents Table 4.5 of this thesis.
Table 6 in the published article represents Table 4.6 of this thesis.

Fig. 1 in the published article represents Figure 4.1 of this thesis.
Fig. 2 in the published article represents Figure 4.2 of this thesis.
Fig. 3 in the published article represents Figure 4.3 of this thesis.

Additional file 1 in the published article represents Appendix 1 of this thesis.

BMC Health Services Research

RESEARCH ARTICLE Open Access

Operating a patient medicines helpline: a survey study exploring current practice in England using the RE-AIM evaluation framework

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Abstract

Background: Patient medicines helplines provide a means of accessing medicines-related support following hospital discharge. However, it is unknown how many National Health Service (NHS) Trusts currently provide a helpline, nor how they are operated. Using the RE-AIM evaluation framework (*Reach, Effectiveness, Adoption, Implementation, and Maintenance*), we sought to obtain key data concerning the provision and use of patient medicines helplines in NHS Trusts in England. This included the extent to which the delivery of helplines meet with national standards that are endorsed by the Royal Pharmaceutical Society (standards pertaining to helpline access, availability, and promotion).

Methods: An online survey was sent to Medicines Information Pharmacists and Chief Pharmacists at all 226 acute, mental health, specialist, and community NHS Trusts in England in 2017.

Results: *Adoption*: Fifty-two percent of Trusts reported providing a patient medicines helpline (acute: 67%; specialist: 41%; mental health: 29%; community: 18%). *Reach*: Helplines were predominantly available for discharged inpatients, outpatients, and carers (98%, 95% and 93% of Trusts, respectively), and to a lesser extent, the local public (22% of Trusts). The median number of enquiries received per week was five. *Implementation*: For helpline access, 54% of Trusts reported complying with all 'satisfactory' standards, and 26% reported complying with all 'commendable' standards. For helpline availability, the percentages were 86% and 5%, respectively. For helpline promotion, these percentages were 3% and 40%. One Trust reported complying with all standards. *Maintenance*: The median number of years that helplines had been operating was six. *Effectiveness*: main perceived benefits included patients avoiding harm, and improving patients' medication adherence.

Conclusions: Patient medicines helplines are provided by just over half of NHS Trusts in England. However, the proportion of mental health and community Trusts that operate a helpline is less than half of that of the acute Trusts, and there are regional variations in helpline provision. Adherence to the national standards could generally be improved, although the lowest adherence was regarding helpline promotion. Recommendations to increase the use of helplines include increasing the number of promotional methods used, the number of ways to contact the service, and the number of hours that the service is available.

Keywords: Patient medicines helplines, RE-AIM, National Health Service, Medicines information, Drug information, Hospital pharmacy, Clinical audit

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Background

Patients often experience changes to their medicines regimen while they are in hospital, and it is healthcare policy in the United Kingdom (UK) to ensure that patients' medicines are managed optimally after discharge from secondary care [1, 2]. However, UK and international research suggest that a substantial proportion of patients who have been discharged from hospital subsequently experience medicines-related problems [3–7]. For example, Lee et al. [3] conducted a study which involved interviewing ninety-six patients after being discharged from one of six acute hospitals in the North-West of England. They found that 36% of patients experienced problems with their medication following discharge, particularly around side effects (63%), and that 26% had actually sought or been given help following discharge, mainly from their general practitioner. Relatedly, UK and international research also show that patients often lack knowledge of their medications following discharge from hospital, particularly around side effects [8–13], and that many patients report not receiving important medicines-related information [14–16]. Results from the 2017 UK National Health Service (NHS) Adult Inpatient Survey found that 30% of 46,795 patients reported that they were not provided with completely clear written or printed information about their medicines, and 43% of 43,719 patients did not recall receiving any information from staff about side effects to look out for when they returned home [17]. Another evident problem which patients may also experience following hospital discharge are medicines-related errors, such as prescribing errors and incorrect or missing information on discharge summary documents [18–20]. In sum, discharge from hospital presents a potentially confusing and/or risky time for the many patients who have recently experienced changes to their medicines.

In many countries, medicines information (MI) services have been established to support patients and the public with questions about their medication [21–25]. In the UK, patient medicines helplines have become available from a number of hospital pharmacies to provide medicines-related support for patients who have received care within secondary healthcare [26, 27]. Patient medicines helplines are typically operated by pharmacy professionals (pharmacists and pharmacy technicians registered with the General Pharmaceutical Council) who specialise in the provision of MI services (from here on, referred to as MI pharmacy professionals) [28]. The first patient medicines helpline in the UK was established in 1992, with the aim of improving patients' knowledge and use of their medicines [29]. In 2007, the Healthcare Commission in the UK reported that, of the 173 acute and specialist NHS Trusts[1] in England, 64% operated a patient medicines helpline, and of 42 mental health Trusts in England and Wales, 31% operated this service [27, 30]. However, over ten years later, it is unknown how many NHS Trusts currently provide a patient medicines helpline.

Recently, several service evaluation studies have been published that provide descriptive information about patient medicines helplines, typically reporting the types of calls received and user satisfaction ratings. Such studies suggest that enquiries predominantly concern issues such as adverse effects, administration and dosage, and interactions [26, 28, 31–33]. Enquiries can also result in patients avoiding harm, such as by highlighting medicines-related errors so that they can be corrected [26, 31, 34]. Evaluations of patients' and carers' experiences of using medicines helplines using self-report surveys suggest that services are thorough and that they found the advice useful, that they felt confident with the information they received, and felt reassured as a result [32–34]. Consequently, patient medicines helplines offer a means of providing medicines-related support following discharge from secondary care, which users find satisfactory [34]. Moving beyond the individual, an additional proposed benefit of patient medicines helplines is that they may reduce the burden on primary care and emergency services [35]. Evaluation studies suggest that, if patient medicines helplines did not exist, enquirers would typically contact their general practitioner to resolve their medicines-related queries [34]. Providing access to a medicines helpline accords with healthcare policy regarding the importance of patients having access to information about their care, and being involved in care-related decisions [36–39]. Additionally, a priority of UK healthcare policy is to improve patients' transitions of care so they are able to manage their own health, and know how to access healthcare support [37–40].

Although service evaluation studies have been conducted to examine patient medicines helplines, to date, no healthcare evaluation frameworks have been applied for the evaluation of this service. Evaluation frameworks are considered to be beneficial, since they provide a structured and guided approach to evaluating an overall program or intervention, and are typically evidence-based [41]. A widely used framework is RE-AIM, which was first published in 1999 [42, 43] and is recommended in Medical Research Council guidance [44]. Whereas most studies focus upon the effectiveness of an intervention, RE-AIM comprises five dimensions that are considered important for evaluating the public health impact of interventions. These are:

- Reach (proportion and representativeness of the population receiving the intervention);
- Effectiveness (assessment of the positive and negative consequences of an intervention);
- Adoption (proportion and representativeness of settings that adopt an intervention);
- Implementation (extent to which an intervention is delivered as intended);

- Maintenance (extent to which an intervention becomes a relatively stable, enduring part of the behavioural repertoire of an individual/organisation).

The 'RE' dimensions are primarily concerned with the impact on the individual (e.g., whether an intervention is beneficial for the people receiving it, and how many individuals who could benefit from it are receiving it). The 'AIM' dimensions are primarily concerned with the impact of an intervention at the level of the intervention setting (e.g., whether sites that could offer the intervention, offer it; whether the intervention is being offered as intended in sites that offer the intervention, and whether this is stable over time). Glasgow and colleagues argued that whilst the 'AIM' dimensions are less often studied, they are equally important factors in determining the impact of an intervention [45].

The main aim of this study was to obtain key data concerning the provision and usage of patient medicines helplines in NHS Trusts in England. The RE-AIM framework was considered particularly useful to achieve this, since patient medicines helpline services could potentially be adopted by all NHS Trusts with the aim of being available for all of a Trust's patients (*Adoption* and *Reach*). Additionally, national standards for setting up and operating a patient medicines helpline in the UK have recently been developed, and are endorsed by the Royal Pharmaceutical Society [46]. This provides the opportunity to evaluate the extent that current practice in the provision of patient medicines helplines meets these standards (*Implementation*).

Using the RE-AIM framework, the following five study objectives were developed (re-ordered so that 'AIM' precedes 'RE', since the existence and delivery of an intervention precedes its use and perceived effectiveness):

1) Establish the percentage of NHS Trusts in England that provide a patient medicines helpline, including the percentages by region, and explore the reasons why some Trusts do not provide this service (*Adoption*).
2) Examine how patient medicines helplines are operated in England, by comparing how current practice meets with national standards for operating patient medicines helplines (*Implementation*).
3) Establish the average number of years that Trusts have operated patient medicines helplines, and the reasons why some Trusts stopped operating a helpline (*Maintenance*).
4) Establish for whom patient medicines helpline services are available, and the average number of enquiries received per week (*Reach*).
5) Establish pharmacy professionals' perceptions as to the benefits that their patient medicines helpline can have (a proxy measure for *Effectiveness*).

Method

Design

This study involved the use of cross-sectional surveys to establish the provision, usage, and current practice in the operation of patient medicines helplines in NHS Trusts in England.

Participants

Inclusion criteria required participants to be either an MI pharmacy professional at an acute, mental health, specialist or community NHS Trust within England whose role involved operating a patient medicines helpline service at their NHS Trust, or a Chief Pharmacist at an acute, mental health, specialist or community NHS Trust within England that operates a patient medicines helpline service. These two professional groups were chosen because MI pharmacy professionals see first-hand the benefits of medicines helplines for patients, and Chief Pharmacists may be better placed to provide a perspective as to how medicines helplines are beneficial within the wider organisation. Additionally, both groups were considered to have insight regarding the operation of their patient medicines helpline service.

At the time of data collection (February–May 2017) 226 NHS Trusts were eligible to be included in the survey. Regional Medicines Information (MI) centres were not invited to participate, since they were contacted prior to data collection and none provided a regional patient medicines helpline that is separate from an NHS Trust.

Materials and procedure

Developing the data collection tools

Two online surveys were developed using SurveyMonkey [47]. SurveyMonkey is a platform for creating online surveys that is compliant with UK data protection laws, and has been used in other pharmacy practice survey research [48, 49]. Best practice guidance for developing and conducting online surveys was sought and adopted during the design and data collection phases of this study [50, 51]. This included writing survey questions and answer options, and considering ethical issues such as providing participants with information about the study and obtaining consent.

Survey 1 was developed to be completed by a lead MI pharmacy professional at each NHS Trusts (or delegated deputy). This was because Survey 1 was tailored to ask questions about the actual operation of the helpline (e.g., the average number of calls per week, and what the advertised hours are), and MI pharmacy professionals typically perform this role. However, if no-one from the

MI team decided to participate, or if the Trust did not have an MI team, Survey 1 was instead sent to the Trust's Chief Pharmacist to complete.

Firstly, Survey 1 sought to establish whether each NHS Trust provides a patient medicines helpline service (*RE-AIM Adoption*). For those Trusts that did not provide a helpline, subsequent questions within Survey 1 focussed on exploring this in more detail (e.g., whether they ever provided a helpline, and if so, the reason/s why the helpline stopped; and the reason/s why their Trust does not currently provide a helpline service). For NHS Trusts that did provide a helpline service, subsequent questions within Survey 1 explored the operation and usage of the service, structured by the remaining RE-AIM dimensions.

To measure *RE-AIM Implementation*, the sections of the national standards for operating patient medicines helplines [46] pertaining to access, availability, and promotion of patient medicines helplines were developed in to questions for inclusion in the survey. The standards for helpline access, availability, and promotion were used, since these sections are most likely to impact helpline service users (other sections pertain to use of standard operating procedures, use of information and professional support, and quality and risk). The standards are separated in to 'satisfactory' and 'commendable' aspects of helpline operation, and both types were included in the survey.

For *RE-AIM Maintenance*, participants were asked to report the year that their helpline service was set up, so that this information could be used to establish the average length of time that helplines have been running.

For *RE-AIM Reach*, participants were asked to report who could use the helpline service, and the number of enquiries received to the helpline service per week.

For *RE-AIM Effectiveness*, MI Pharmacy professionals' and Chief Pharmacists' perceptions as to the benefits of patient medicines helpline services were sought. A list of potential benefits of patient medicines helplines has been developed by the same small working group of proponents of the service that developed the national standards, and have also been endorsed by the Royal Pharmaceutical Society [35]. These proposed benefits were included in Survey 1, and were the primary feature of Survey 2. Participants' options were to rate each item as having 'major benefit' or 'minor benefit'/'no benefit'. Participants were also given the option to report any additional perceived benefits that were not included in the list.

Survey 2 was developed to be completed by Chief Pharmacists (or delegated deputy) at Trusts that operate a medicines helpline, where Survey 1 had already been completed by an MI pharmacy professional. The aim of Survey 2 was to explore Chief Pharmacists' perspectives as to how patient medicines helplines are beneficial, since Chief Pharmacists may be more likely to take a wider organisational view than those involved in the day-to-day operation of the helpline service. The primary feature of Survey 2 was therefore the *RE-AIM Effectiveness* section of Survey 1.

Overall, survey questions primarily consisted of either yes/no or multiple-choice answers, although some questions also provided free-text boxes. The questions and response options for Survey 1 and Survey 2 are provided in Additional file 1.

Pre-test and pilot

Following recommended methods [52], a pre-test of the survey was conducted, with three pharmacists with expertise in the area of patient medicines helplines. The aim of the pre-test was to assess the content, length and format, and to identify problems that may interfere with respondents completing the survey consistently and accurately. Amendments were made based upon the feedback of the pre-test.

Additionally, prior to study commencement, a pilot study was conducted. The pilot involved collecting survey data using a randomly selected 10% of the main study sample, ensuring that Trust type and geographical coverage of England were represented. The results of the pilot suggested that no changes were necessary, so data from the pilot were included in the final results.

Data collection

Figure 1 shows the procedure for collecting data using the two surveys.

Data were collected between February–May 2017. Survey 1 was sent to MI pharmacy professionals at all acute, mental health, specialist, and community NHS Trusts in England, via email. If Survey 1 was not completed by an MI pharmacy professional, it was sent to the Chief Pharmacist of the NHS Trust, via email. If Survey 1 was completed by an MI pharmacy professional, and if the Trust reported providing a patient medicines helpline, the Chief Pharmacist of the Trust received Survey 2. For all participants, three reminder emails were sent if there was no response, within two weekly intervals. Non-responders were contacted to establish whether or not their Trust provided a helpline. Participants were informed that by completing the survey, they would have the option of being included in a prize draw to win a £25 gift voucher.

Data analysis

Data were analysed using SPSS version 23, to primarily produce descriptive statistics (e.g., percentages of NHS Trusts complying with the standards). Chi square tests of independence were used to examine the relationships between Chief Pharmacists' and MI pharmacy professionals' ratings of the benefits of patient medicines helplines. To establish the percentage of NHS Trusts which

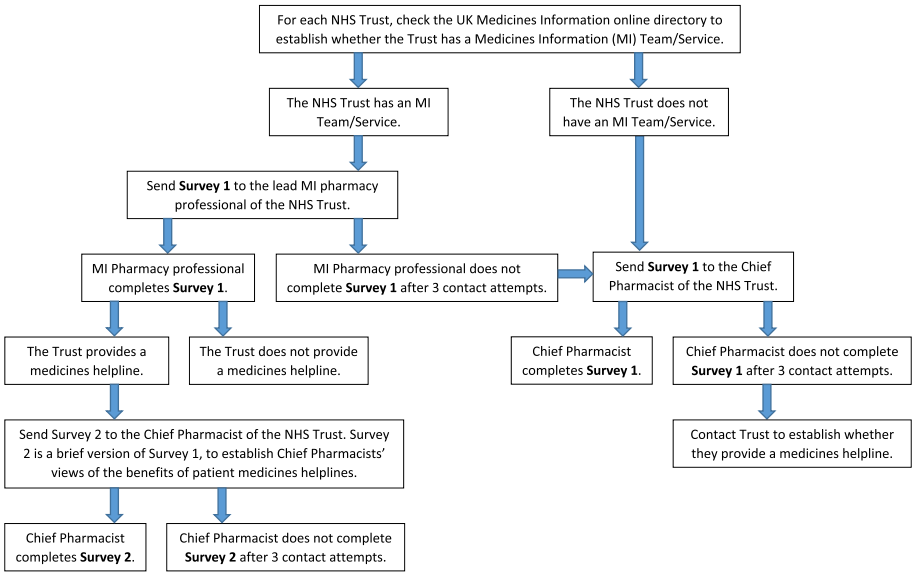

Fig. 1 Data collection procedure

provide a patient medicines helpline by region of England, an official list of NHS Trusts within ten regions of England was used [53].

Results

Response rates

Out of 226 NHS Trusts, 202 completed Survey 1 (89%). Of these, 127 (63%) were completed by an MI pharmacy professional, and sixty-two (31%) were completed by a Chief Pharmacist (thirteen did not disclose their job title; 6%). The remaining 11% of Trusts were contacted to establish whether they operated a patient medicines helpline, with all such trusts providing a response to this item. Of the survey non-responders, eleven were from mental health Trusts (46%; 20% of all mental health Trusts), seven were from acute Trusts (29%; 5% of all acute Trusts), five were from community Trusts (21%; 29% of all community Trusts) and one was from a specialist Trust (4%; 6% of all specialist Trusts).

Additionally, fifty-two Chief pharmacists also completed Survey 2 comprising the questions about the benefits of providing a helpline service.

RE-AIM 'adoption'

Table 1 shows the percentage of NHS Trusts in England that provide access to a patient medicines helpline, by Trust type and region. Combined, 52% of NHS Trusts provide this service (acute, 67%; specialist, 41%; mental health, 29%; and community, 18%).

Out of the 117 Trusts that provided a patient medicines helpline, 110 answered whether they operated the service directly or via another Trust. Three out of 110 Trusts reported providing the helpline service via another Trust (3%). Of the 107 Trusts which operated their own helpline, 103 Trusts operated one helpline (96%), three Trusts operated two helplines (3%) and one Trust operated three helplines (1%). Table 2 reports the percentages of where patient medicines helpline services are located within NHS Trusts, showing that helplines are predominantly located within MI centres (87%).

Table 1 NHS Trusts in England providing access to a patient medicines helpline service

Type of NHS Trust/region of England	Percentage of NHS Trusts providing access to a helpline[a]
Acute Trust	67% (91/136)
Specialist Trust	41% (7/17)
Mental health Trust	29% (16/56)
Community Trust	18% (3/17)
Total NHS Trusts	52% (117/226)
East of England	72% (18/25)
South Central	69% (9/13)
South East	69% (11/16)
London	60% (21/35)
North East	60% (6/10)
Yorkshire & Humber	52% (11/21)
South West	46% (11/24)
North West	41% (16/39)
East Midlands	33% (5/15)
West Midlands	32% (9/28)

[a]Numbers in parentheses show the actual numbers of NHS Trusts that reported providing access to a helpline, out of the total number of Trusts, for the type of Trust or the region of England

Table 2 Location of patient medicines helpline services within NHS Trusts in England

Location of the helpline service within the NHS Trust	Percentage of NHS Trusts providing their helpline from the specified location[a]
Medicines Information Centre	87% (97/112)
General clinical pharmacy services	13% (15/112)
Dispensary	4% (5/112)
Specialist clinical pharmacy services	4% (4/112)

Note. Nine Trusts reported that their helpline service was provided by more than one location within the NHS Trust (8%), which is why the total exceeds 100%

[a]Numbers in parentheses show the actual numbers of NHS Trusts that reported providing their helpline from the specified location, out of the total number of NHS Trusts which reported providing access to a helpline and answered this survey question

Of the 109 non-helpline Trusts, seventy-six provided comments as to why they do not offer the service. For fifty-four of the seventy-six, the reason was a lack of resources (staff time and/or funding; 71%). For sixteen of the seventy-six, the reason was not having a MI service (21%). Three Trusts answered that they do not have a helpline because they do not know what the demand would be (4%). Six per cent reported that their Trust has plans to provide a patient medicines helpline in the future, whereas 56% reported that this was a possibility, and 38% reported that their Trust did not have any plan to provide this service in the future.

Of the non-helpline Trusts, 90% reported that, if they did receive a call from a discharged patient about their medicines, they would answer the query.

RE-AIM 'implementation'

Tables 3, 4 and 5 shows the percentages of NHS Trusts which were found to comply with the national standards for helpline access, availability and promotion.

Of the 107 NHS Trusts that answered all questions pertaining to the helpline access standards, sixteen NHS Trusts were fully compliant with all access standards (15%; 54% were compliant with all 'satisfactory' standards, and 26% were compliant with all 'commendable' standards). Of the 107 NHS Trusts that answered all questions pertaining to the helpline availability standards, five NHS Trusts were fully compliant with all availability standards (5%; 86% were compliant with all 'satisfactory' standards, and 5% were compliant with all 'commendable' standards). Of the ninety-nine NHS Trusts that answered all questions pertaining to the helpline promotion standards, two NHS Trusts were fully compliant with all promotion standards (2%; 3% were compliant with all 'satisfactory' standards, and 40% were compliant with all 'commendable' standards).

Out of the ninety-nine Trusts that answered all questions pertaining to the 'satisfactory' national standards, one NHS Trust was fully compliant with all 'satisfactory' standards (1%). Out of the 106 Trusts that answered all questions pertaining to the 'commendable' national standards, two NHS Trusts were fully compliant with all 'commendable' standards (2%). From a total of ninety-nine Trusts that answered all questions pertaining to both 'satisfactory' and 'commendable' national standards, one Trust was fully compliant with all standards (1%). Figure 2 shows the percentages of NHS Trusts that were found to comply with all of the national standards for helpline access, availability and promotion.

Table 3 Compliance with national standards for 'satisfactory' and 'commendable' levels of patient medicines helpline access

National standards: Helpline access		Percentage of NHS Trusts meeting each standard[a]
'Satisfactory' standards	Calls charged at local rate or Freephone (not a premium number).	99% (108/109)
	The phone line allows direct dialling from outside.	97% (106/109)
	An answerphone allows a message to be left outside of advertised hours.	81% (88/108)
	Contact with a pharmacy professional is always available during advertised hours.	71% (77/108)
	Total compliance with access 'satisfactory' standards.	54% (58/108)
'Commendable' standards	The helpline has a dedicated phone number.	60% (65/109)
	There is access to the service by means other than telephone, such as email, webform, personal visit[b].	39% (42/109)
	Total compliance with access 'commendable' standards.	26% (28/107)
Total compliance with both 'satisfactory' and 'commendable' access standards		15% (16/107)

Note. Although 117 of 226 acute, mental health, specialist, and community NHS Trusts reported providing a patient medicines helpline, not all NHS Trusts answered every survey question

[a]Numbers in parentheses show the actual numbers of NHS Trusts that met the standard, out of the total number of Trusts which answered the survey question pertaining to the standard

[b]Thirty-four Trusts reported advertising their service as being accessible via one other method besides the telephone (31%), and eight Trusts reported advertising their service as being accessible via two other methods besides the telephone (7%). At thirty-four Trusts, their service was advertised as being accessible via email (31%). At eight Trusts, their service was advertised as being accessible via online web form (7%). At seven Trusts, their service was advertised as being accessible face-to-face (6%). At one Trust, their service was advertised as being accessible via social media (Twitter; 1%)

Table 4 Compliance with national standards for 'satisfactory' and 'commendable' levels of patient medicines helpline availability

National standards: Helpline availability		Percentage of NHS Trusts meeting each standard[a]
'Satisfactory' Standards	The helpline is available five days per week.	96% (103/107)
	The helpline is accessible to patients/carers for minimum of four hours per day.	86% (92/107)
	Total compliance with availability 'satisfactory' standards.	86% (92/107)
'Commendable' Standards	The helpline is available for eight hours or more per day.	57% (61/107)
	The helpline is available for extended hours (i.e., evenings, weekends[b]).	7% (7/107)
	Total compliance with availability 'commendable' standards.	5% (5/107)
Total compliance with both 'satisfactory' and 'commendable' availability standards		5% (5/107)

Note. Although 117 of 226 acute, mental health, specialist, and community NHS Trusts reported providing a patient medicines helpline, not all NHS Trusts answered every survey question

[a]Numbers in parentheses show the actual numbers of NHS Trusts that met the standard, out of the total number of Trusts which answered the survey question pertaining to the standard

[b]Three of 107 (3%) helpline services were reported as being available in the evenings; five of 107 (5%) helpline services were reported as being available at weekends (and operate seven days per week)

RE-AIM 'maintenance'

The median time that an NHS Trust had been operating a patient medicines helpline in England was six years (range 1–24 years).

Out of the 109 NHS Trusts which reported that they do not currently provide a patient medicines helpline, eighty-eight Trusts answered whether or not they provided a helpline in the past. Nine responded that they operated a helpline in the past (10%), citing main reasons for discontinuing the service as a lack of resources (lack of staff and/or funding; five of nine; 56%), and insufficient use (two of nine; 22%).

RE-AIM 'reach'

Results showed that out of the 117 NHS Trusts that provided a patient medicines helpline, 112 Trusts answered who could access the helpline. Figure 3 shows the provision of access to medicines helplines for different groups of individuals. Medicines helplines are primarily available for discharged inpatients (98% of NHS Trusts), outpatients (95% of NHS Trusts), and patients' carers (93% of NHS Trusts).

One hundred and seven participants reported the number of enquiries typically received to their patient medicines helpline service per week. For all Trust types combined, the median number of enquiries received per week was five (range 0–50). For acute Trusts, the median was five enquiries. For mental health Trusts, the median was three enquiries. For specialist Trusts, the median was seven enquiries. The median number of enquiries for community Trusts could not be robustly calculated due to the low number of community Trusts which operated a helpline and which answered this question.

Table 5 Compliance with national standards for 'satisfactory' and 'commendable' levels of patient medicines helpline promotion

National standards: Helpline promotion		Percentage of NHS Trusts meeting each standard[a]
'Satisfactory' Standards	The helpline is promoted at all of the healthcare organisation's sites.	59% (64/109)
	Promotional materials identify access times and types of enquiries patients/carers can make.	40% (44/109)
	The helpline is promoted to discharged inpatients by methods agreed with patients locally.	6% (6/100)
	Total compliance with promotion 'satisfactory' standards.	3% (3/100)
'Commendable' Standards	The helpline is also promoted to outpatients.	84% (91/108)
	Additional promotional methods are used, such as patient leaflets and the NHS Trust website[b].	42% (46/109)
	Total compliance with promotion 'commendable' standards.	40% (43/108)
Total compliance with both 'satisfactory' and 'commendable' promotion standards		2% (2/99)

Note. Although 117 of 226 acute, mental health, specialist, and community NHS Trusts reported providing a patient medicines helpline, not all NHS Trusts answered every survey question

[a]Numbers in parentheses show the actual numbers of NHS Trusts that met the standard, out of the total number of Trusts which answered the survey question pertaining to the standard

[b]Eighty-two Trusts reported that their helpline was promoted using leaflets or business cards that are given to patients (75%). Forty-two Trusts reported that their helpline was advertised on the Trust website (38%). Forty Trusts reported that their helpline was promoted on medicines labels or on medicines bag labels (37%). Thirty-six Trusts reported that their helpline was promoted on the patient's discharge summary (33%). Thirty Trusts reported that their helpline was promoted using posters in clinical areas (27%). Twenty-two Trusts reported that staff routinely tell patients about the helpline (20%). The median number of promotional methods used was two. The maximum number of promotional methods used by a single Trust was seven

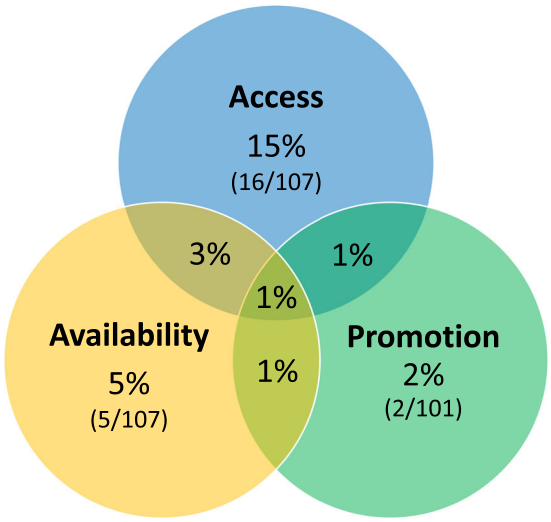

Fig. 2 Total compliance with national standards for patient medicines helpline access, availability, and promotion. *Note.* Numbers in parentheses show the actual numbers of NHS Trusts that met the standards, out of the total number of Trusts that answered the survey questions pertaining to the standards

RE-AIM 'effectiveness'

Table 6 provides an overview of pharmacy professionals' perceptions regarding the major benefits of their helpline service. The top five perceived benefits were: avoiding harm to patients (88%), improving patient medication adherence (85%), providing assurance that patients can access professional help from home (83%), improving the patient experience (e.g., patient satisfaction; 80%), and supporting patient discharge (76%). Chi square tests showed that there was a significant association between professional role and benefit rating for two of the perceived benefits: avoiding harm to patients ($\chi^2(1) = 5.65$, $p = .017$), and identifying errors ($\chi^2(1) = 9.39$, $p = .002$). For both, MI pharmacy professionals were more likely to rate the benefits as being major benefits compared to Chief Pharmacists.

Exploratory analyses

The median number of five helpline calls per week per NHS Trust was considered by our research team to be low. Exploratory analyses were conducted to explore potential ways to increase helpline use, pertaining to the areas of helpline access, availability and promotion. In order to normalise the data so that parametric tests could be conducted, the data were transformed using a log transformation. Pearson's partial correlation coefficients were calculated to establish the relationships between the number of hours that helplines were available per week and the number of enquiries received per week, and between the number of promotional methods used and the number of enquiries received per week. The size of NHS Trusts was controlled using Hospital Episode Statistics 'Finished Admission Episodes' for 2015–2016 [54]. Significant positive correlations were found between the two sets of variables (r (95) = .31, $p = .002$ and r (98) = .23, $p = .02$, respectively). Additionally, an analysis of covariance was calculated to establish whether there was a statistically significant difference between the number of enquiries per week for Trusts that only provide access to their service via the telephone (mean number of enquiries per week = 7.0, SD = 8.8) versus Trusts that also provide access via at least one other method of communication (mean number of enquiries per week = 9.9, SD = 9.7). There was a significant effect of number of communication methods on the number of calls after controlling for Trust size, $F(1, 99) = 8.89$, $p = .004$, $\eta^2 = .073$.

Discussion

This study used the RE-AIM healthcare interventions evaluation framework to establish the provision, usage, and current practice in the operation of patient

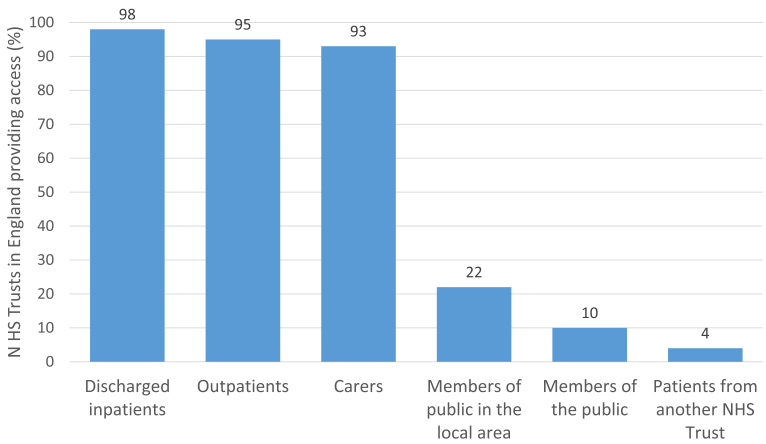

Fig. 3 Provision of access to medicines helplines for different groups of individuals ($n = 112$)

Table 6 Pharmacy professionals' perceptions of the benefits of patient medicines helpline services

Proposed benefits of patient medicines helplines	% who see it as a major benefit		
	MI pharmacy professionals ($n = 87$)	Chief Pharmacists ($n = 66$)	Total ($n = 156$[a])
Avoiding harm to patients (e.g., adverse effects, interactions).	93%[b]	80%[b]	88%
Improving patient medication adherence.	89%	80%	85%
Providing assurance to patients that they can access professional help from home.	84%	80%	83%
Improving the patient experience (e.g., patient satisfaction).	84%	76%	80%
Supporting patient discharge.	78%	71%	76%
Optimising medicines.	76%	73%	75%
Identifying errors.	85%[c]	64%[c]	75%
Reducing medicines-related readmissions.	67%	62%	65%
Learning from adverse patient experiences.	55%	56%	55%
Reducing visits to other healthcare services (e.g., GPs, A&E).	52%	53%	51%
Helping the organisation avoid complaints and possible litigation.	44%	42%	43%
Adhering to the NHS constitution (e.g., patients have a right to receive information).	40%	30%	37%
Improvement in Trust targets and in national surveys.	22%	26%	23%

Note. Although 117 of 226 acute, mental health, specialist, and community NHS Trusts reported providing a patient medicines helpline, not all NHS Trusts answered every survey question. Respondents were also provided a free-text box to record other perceived benefits. However, these suggestions were not included in the results since they were either a rewording of an item already in the list, or not also suggested by any other respondents

[a]Not all respondents provided their job title, which is why the total is greater than the number of MI pharmacy professionals and Chief Pharmacists combined

[b]A Chi square test of independence showed that there was a significant association between professional role and rating, at $p < .05$

[c]A Chi square test of independence showed that there was a significant association between professional role and rating, at $p < .005$

medicines helplines in NHS Trusts in England, and pharmacy professionals' perceptions of the main benefits of their service.

Regarding the adoption of patient medicines helplines, this study shows that there is disparity of access to the service within England. Just over half of acute, mental health, specialist and community Trusts in England operate a patient medicines helpline service, although this varies according to type of Trust and region. Only 29% of mental health Trusts and 18% of community Trusts currently provide their patients with access to this service. The percentage of acute Trusts which provide a patient medicines helpline is over double that of mental health and community Trusts. This implies that the benefits of patient medicines helplines (i.e., reduced patient harm, and error correction) [26, 31, 34] are currently not experienced to the same extent for patients of mental health and community services, compared to patients of acute and specialist services. Additionally, the proportions of Trusts in the North and Midlands of England which provide the service is typically lower than the proportions of Trusts in the southern regions of England. We also found that nine Trusts reported previously operating a helpline that had been discontinued. The main reason for closure was a lack of resources/funding. Lack of resources/funding was also the main reason why 48% of Trusts did not currently provide a helpline, suggesting that this is an important barrier to providing this service. However, regarding the maintenance aspect of patient medicines helplines, our findings suggest that, once adopted, helplines are likely to become a relatively stable service for NHS Trusts. On average, NHS Trusts had been operating for six years, with the longest running for twenty-four years.

Our findings suggest that the reach of patient medicines helpline services could be improved. In the UK, up to 44% of patients who have been discharged from hospital may subsequently experience medicines-related problems [3, 4]. Given that there is an identified need for medicines information and a high number of hospital patients [54], the number of patients who use medicines helplines per week should be substantial. However, we identified that the median number of enquiries per Trust was five per week. This finding, along with similar results from previous studies, suggest that patient medicines helplines are an underused service [26–28].

Patient medicines helplines are considered to be beneficial because they have the potential to reduce the burden upon other services, including GP and A&E visits, and also to potentially reduce the number of medicines-related hospital readmissions [35]. This is topical, given that the average waiting time from booking a standard appointment to seeing a GP in England in 2016 and 2017 was estimated to be approximately two weeks [55]. Also, in the UK, the Department of Health recognises that urgent care services are struggling to cope with rising demands [40, 56]. In January 2017, and again in December 2017, the proportion of patients waiting longer than four hours in A&E reached

its highest level since the collection of A&E performance data began [57]. There is also recognition that a proportion of A&E visits could be managed more appropriately elsewhere. For example, 38% of people who attend A&E receive guidance or advice only [58]. The 2014 NHS Five Year Forward View, which provides an outline for improving and modernising the NHS, emphasises that reducing the workload in A&E is a priority [40, 56]. It would therefore be beneficial to examine why patient medicines information helplines are underused, and to consider how it might be possible to encourage their use.

Our findings regarding the implementation of patient medicines helplines, whereby we compared current practice to recommended national standards for operating patient medicines helplines, may indicate why this service is underused. The access, availability, and promotion of helplines are all likely to influence their use, and we found that adherence to the national standards could be improved in all three areas. However, the greatest discrepancy between current practice and the national standards concerns the promotion of helplines. For example, promotional material containing information relating to medicine helpline access times and the types of enquiries that patients/carers can make were used in only 40% of Trusts. Not providing this information may cause frustration for callers who call outside of operating hours, and may cause confusion as to what the service provides and whether it can cater to their needs. The main reason why overall adherence to the 'promotion' national standards was particularly low, was because very few Trusts sought the advice of patients regarding the promotional methods to use. Including patients and carers in the development of healthcare services is increasingly recognised as being beneficial for understanding what works and why, in order to improve services [59]. Involving service users may therefore be beneficial for improving not only helpline promotion, but all aspects of this service. Our findings also suggest that increasing the number of promotional methods may increase the use of patient medicines helplines, since the number of methods was significantly correlated with number of enquiries. Additionally, helplines are typically not promoted at all hospital sites, and so this may be another potential explanation for their lack of use.

Regarding helpline access and availability, 43% of medicines helplines are available for less than eight hours a day, and at 29% of sites, a pharmacist is not always available. Therefore, service users may not be able to immediately speak to a pharmacist, and it is unknown what effect this has upon enquirers. For example, do enquirers try accessing the helpline again later or do they perhaps seek support elsewhere? We also found that approximately only 7% of Trusts that operate a helpline currently provide the service out of hours (e.g., evenings and/or weekends). For comparison, a recent survey study found that 87% of hospitals at acute and mental health Trusts in England provide an out-of-hours pharmacy advice service for healthcare professionals [60]. Our findings also show that approximately only 5% of Trusts that operate a helpline currently provide the service seven days per week. Since the number of hours per week that a helpline is open correlates with the number of enquiries received per week, another way to increase the use of patient medicines helplines may be to increase the number of hours per week that the service is available.

Our results suggest that approximately only 39% of NHS Trusts that operate a patient medicines helpline advertise the service as being accessible via at least one other method of communication besides the telephone, with the main alternative method being email. Providing access via at least one other means of communication besides the telephone was found to significantly increase the number of calls per week, albeit slightly, suggesting that this could be another way of increasing helpline use. Only one NHS Trust reported advertising their service as being accessible via social media. Service evaluation studies that have examined the types of people who call patient medicines helplines suggest that the majority are elderly [26]. In order to better engage with younger people, MI services may benefit from also providing more current methods of communication. Research carried out internationally has begun to examine alternative methods of providing MI to patients and members of the public, including online 'Ask the Pharmacist' services [61], and a Facebook 'Pharmacist Hour' [62].

Regarding the effectiveness of patient medicines helplines, we found their main perceived major benefits to be avoiding harm to patients, improving patient medication adherence, and providing assurance that patients can access professional help from home. Service evaluation studies have been conducted which provide evidence that enquiries to patient medicines helplines can result in patients avoiding harm [31], and that between 95 and 97% of enquirers subsequently report following the advice given [32, 34]. The only significant differences found between Chief Pharmacists' and MI pharmacy professionals' endorsements of the major benefits were for avoiding harm to patients, and identifying errors. This could be because MI pharmacy professionals have first-hand experience of interacting with helpline callers to know the types of enquiries being made and the impact they can have. Interestingly, reducing visits to other healthcare services (e.g., GPs, A&E) was considered a major benefit by only 51% of respondents. However, this could be because the number of enquiries per week per Trust was found to be relatively low, and so the reduction of visits to other services would likely be minimal (several respondents reported this as the reason for their response, in the 'other comments' section of the survey). Increasing the use of patient medicines helplines may shift pharmacists' perceptions in this respect.

The list of benefits was originally developed by a small working group of proponents of patient medicines helplines [35]. This study provides stronger evidence as to the major benefits of patient medicines helplines, as perceived by a sample of 156 pharmacy professionals with expertise in patient medicines helpline provision.

Recommendations

In order to increase the impact of patient medicines helplines, we encourage helpline providers to consider ways to increase their use. Our findings suggest that this may be achievable by improving the access, availability, and promotion of helplines. For example:

- Providing access to the service by other means in addition to the telephone, such as email, webform via the Trust website, online chat, and Skype.
- Extending the hours of availability, such as providing access to the service beyond typical 9–5 working hours (e.g., evenings and weekends).
- Increasing the number of promotional methods, and/or conducting local improvement projects to establish the types of promotional methods that patients and carers recommend, and would most likely see and remember.
- Promoting the service at all sites within the organisation, and ensuring that promotional methods identify access times and types of enquiries that can be made.

Limitations and future research

A limitation of our study is that we were not able to obtain a full dataset, since some respondents chose not to fully complete all survey questions. Although missing data was minimal, the percentages presented in this study can only be considered to be approximately representative of the total number of NHS Trusts. Another limitation is that, in order to minimise respondent burden, we chose to only include questions that represented the sections of the national standards pertaining to helpline access, availability, and promotion. However, it would be advantageous for a future study to audit the remaining standards, since this may highlight additional ways that helpline providers may improve the delivery of their service. Subsequent research could also audit how helplines are operated in the other three UK countries, and collect additional data to explore some of the RE-AIM dimensions in greater depth. For example, a more thorough approach for understanding the reach of patient medicines helplines would be to follow up a cohort of discharged patients from Trusts that provide a medicines helpline, in order to explore those patients who subsequently require medicines information, and to compare the percentages and characteristics of helpline users with patients who choose alternative sources of support. This study design could also provide an opportunity to explore patients' reasons for not seeking medicines information via the medicines helpline service.

Future research could also seek to establish whether and in what ways the variability in the operation of patient medicines helplines has an effect upon service users, and qualitative methods would be appropriate for exploring patients' and carers' experiences of using this service. Exploring the experiences that service users have regarding their medicines following their use of a patient medicines helpline could also provide further evidence as to the effectiveness of this service. Our measure of the effectiveness of helplines was limited, since it relied upon the perceptions of service providers and may be biased if participants were apprehensive about reporting any negative or poor aspects of their service. Additionally, our survey did not include a question to specifically ask pharmacy professionals to also provide their perceptions as to how patient medicines helpline services could be improved. However, our findings regarding the benefits of helplines provide a useful starting point to identify potential areas for future research. For example, studies could be designed to empirically test whether the perceived benefits of helplines are indeed benefits.

Although we have provided recommendations for increasing the use of patient medicines helplines, we acknowledge that increasing their use will likely require additional resources, and we found that a lack of staffing/funding was the main reason for NHS Trusts not providing a helpline, and for ceasing previously existing helplines. Future research could seek to establish whether a more cost-effective yet acceptable approach might be to operate a network of regional patient medicines helplines, or a national service, with collaboration from NHS Trusts for enquiries requiring local resources. However, a recent study by Badiani et al. [34] found that, out of 200 enquiries to their patient medicines helpline service, 75% required access to local knowledge. The most commonly used local source was the patients' electronic medical records (73%), followed by contacting a healthcare professional involved in the patient's care (34%). Badiani et al. conclude that their findings support the value of having a network of local PMHS, rather than a small number of centralised services. Further research is needed to establish the generalisability of this finding.

Conclusion

This study demonstrates that patient medicines helplines continue to be provided by over half of NHS Trusts in England, with a similar percentage as reported by the Healthcare Commission in 2007. Also, the percentages

of mental health and community Trusts that operate a helpline were found to be less than half of the percentage of acute Trusts that operate a helpline. Combined, these findings show that not all patients are able to experience the benefits that patient medicines helplines provide, due to a lack of adoption of this service. Adherence to the national standards could generally be improved, although the lowest adherence was regarding helpline promotion. Since patient medicines helplines appear to be an underused service, improving helpline access, availability and promotion may help to increase their use. However, the most cited reason for the lack of a helpline in 48% of NHS Trusts in England is lack of resources. This is also the main reason why some NHS Trusts stopped operating a helpline. Without adequate resources, it may therefore be that helpline providers do not currently have the capacity to increase the use of their service. One option could be to pool resources within regions, although this may not be possible given that many enquiry answers require local knowledge from the hospital where the patient received care. Further research is needed to explore the best way to support all patients who need help with their medicines following hospital discharge, which is cost-effective without diminishing quality.

Endnotes

[1]The English National Health Service (NHS) is organised in to NHS Trusts, which are organisations that provide goods and services for the purposes of health care (e.g., hospital and community services), and each Trust primarily serves a geographical area within England.

Additional file

Additional file 1: Survey questions. Questions and answer options for Survey 1 and Survey 2. (PDF 677 kb)

Abbreviations

A&E: Accident and emergency; GP: General practitioner; MI: Medicines information; NHS: National Health Service; RE-AIM: Reach, Efficacy/effectiveness, adoption, implementation, and maintenance; UK: United Kingdom

Acknowledgements

We would like to thank the following individuals for providing feedback on the survey data collection tool: Trevor Beswick, formerly Director of South West Medicines Information & Training at University Hospitals Bristol NHS Foundation Trust; Simon Wills, Head of Southampton Medicines Advice Service, University Hospital Southampton NHS Foundation Trust; and Angela Badiani, Research and Training Pharmacist at Southampton Medicines Advice Service, University Hospital Southampton NHS Foundation Trust.

Funding

The lead author was funded by a Graduate School Scholarship provided by the University of Bath. The funder had no role in the study design, the collection, analysis and interpretation of the data, the writing of the report, and the decision to submit the article for publication.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available, for data privacy and ethical considerations.

Authors' contributions

The study was designed by MW and MJ, with advice from AJ and JS. MW collected all data, conducted the analyses, and drafted the manuscript. All authors read, provided feedback and approved the final manuscript.

Ethics approval and consent to participate

Prior to study commencement, ethical approval was obtained from the Research Ethics Approval Committee for Health at the University of Bath (Ref: EP 16/17126). Health Research Authority approval was not sought as the study was deemed to be audit and evaluation by the South West NHS Research Design Service. Informed consent was provided by participants when they ticked a consent box in the online survey that was presented immediately after the participant information page.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 7 March 2018 Accepted: 5 November 2018
Published online: 20 November 2018

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4.4 Data access statement

As specified in the article, the datasets generated and analysed for this study are not publicly available, for data privacy and ethical considerations. This is because the participant consent form did not ask participants to agree to share their anonymised data for future research.

4.5 Chapter 4 summary

This study has been a useful foundation for the PhD, in order to provide key background information pertaining to the provision, implementation, use, longevity, and perceived effectiveness of PMHS. At the time of data collection in 2017, approximately half of NHS Trusts provided this service, and there was variability in the way that PMHS were provided. Additionally, the promotion, availability, and access of PMHS were not meeting national standards regarding PMHS implementation. This may have affected their use, considering that PMHS only received an average of five calls per week. However, PMHS were perceived to have a number of benefits, by pharmacy professionals who provided them (e.g., patients can avoid medicines-related harm, medication errors can be corrected and learnt from, and patients' medication adherence can be improved). Once established, PMHS tended to become a stable service for NHS Trusts, with Trusts providing the service for six years on average.

For transparency, the qualitative aspects of the study (i.e., participants providing written comments as to why their Trust does not provide a PMHS, and participants providing comments as to why their PMHS ceased to exist) were analysed using content analysis (6). This involved coding all comments and using the coded data to establish the proportion of participants who's comments were in agreement regarding a particular code (e.g., 71% of participants commented that the reason why their Trust did not provide a PMHS was due to a lack of resources; 16% of participants commented that the reason why their Trust did not provide a PMHS was because their Trust does not have a medicines information department).

A strength of this study was the high response rate of the survey. In order to increase the response rate, a Cochrane review by Edwards et al. was used, which describes evidence-based methods for increasing responses to online surveys (7). Based upon this review, the strategies I used were: offering incentives (participants

had the opportunity to win one of two £25 gift vouchers), sending the survey out 2-3 times (I sent the survey out 3 times to non-responders), personalising the invite (I sent the email invites to participants personally, using their names, as established via the UKMi online directory (8)), not making the survey lengthy (I tested the survey beforehand to ensure it was considered an appropriate length), having a survey that is of interest to the potential participants (the survey pertained to the provision of PMHS, and was being sent to providers of PMHS), using textual presentation of response categories instead of visual presentation of response categories (I always used the former type), including a statement that others had responded (I sought to increase the response rate of non-acute Trusts by mentioning the low response rate from non-acute Trusts in their second and third email invites), and not using the word 'Survey' in the subject line of the email (I used the term 'online study' instead). Strategies that the Cochrane review found were beneficial yet were not used in my study were: sending a picture in the invite email (I thought this may look unprofessional), and having a female researcher send the email invite compared to a male researcher (I was the lead researcher, and male).

The study presented in this chapter found that 52% of Trusts provide a PMHS, and 48% of Trusts do not. A stepped-wedge randomised trial design may be used to evaluate healthcare services that are already being provided but where the evidence for the effectiveness of the service is limited (9). A stepped-wedge design could therefore be suitable for evaluating the effectiveness of PMHS. Additionally, it may be possible to compare Trusts that provide a PMHS to Trusts that do not, for example, on medicines-related 30-day hospital readmissions. However, the study presented in this chapter also found that, on average, NHS Trusts receive just five enquiries to their PMHS per week. The low usage of PMHS suggests that the above study designs would be unlikely to detect an effect, if any exist.

Part of the study involved exploring how PMHS are being delivered, including whether current practice met national standards for PMHS provision. However, a limitation of this aspect of the study is that the standards were developed by a small group of MI pharmacists based primarily at one NHS Trust that provide a PMHS. Therefore, the national standards may not be free from bias (e.g., the standards may reflect what is considered good practice in relation to the PMHS provided by the developers of the standards, which may not be endorsed by the wider MI community). Relatedly, the document containing the national standards does not provide any information regarding their development to ascertain whether

they are evidence-based. For example, one of the standards proposes that alternative methods of accessing the service should be provided, such as email or webform. Yet, the decision to include email and webform options within this standard is not reported as being based upon prior evidence, and therefore their implementation in order to meet this standard may be a waste of time and resources.

Another limitation of this study is that the effectiveness of PMHS was measured by examining pharmacy professionals' perceptions of the major benefits of PMHS. Since this is an exploration of the perceptions of effectiveness, rather than hard outcomes (e.g., readmissions, reduced symptoms, improved health), the findings may be biased (i.e., response bias). For example, it could be argued that pharmacy professionals have a vested interest in making PMHS appear beneficial, since their livelihood may be dependent (to some extent) upon the continued provision of this service. They may therefore have reported benefits as being 'major' even if they do not typically perceive them that way. Relatedly, 'major benefit' was chosen as the term used for participants to rate the effectiveness of their service. However, the word 'major' as a quantifier could be interpreted differently by different participants, since it is subjective.

A limitation of survey methods for examining PMHS, however, is that participants do not have the opportunity to describe in depth their experiences of providing this service. For example, it would be useful to explore further the reasons *why* NHS Trusts provide their PMHS with limited promotion and availability. It would also be useful to explore pharmacy professionals' perceptions as to why the use of PMHS may be inadequate, and for them to describe their perceptions pertaining to the effectiveness of PMHS in their own words, rather than selecting from a pre-specified list (as was the case in this survey study). Qualitative methods would therefore be useful to achieve this. However, it is unknown whether any qualitative work has been conducted on this topic. Additionally, further work could be conducted to provide a foundation for this PhD topic by systematically reviewing the available literature pertaining to PMHS. This would establish whether any qualitative work had been conducted, and would also highlight other gaps in the evidence-base for future research regarding PMHS. Systematically reviewing the available literature could also provide further insight into the effectiveness of this service. Therefore, what follows next is a systematic review examining the evidence regarding the effectiveness of PMHS.

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Chapter 5: A systematic review examining the effectiveness of medicines information services for patients and the general public.

5.1 Overview of Chapter 5

This chapter presents the second study of this doctoral research. As with Study 1, this second study also provides the foundations for future research examining PMHS. Studies that have examined PMHS have typically been service evaluations of individual sites to describe the characteristics of enquirers and their enquiries, and to report the effectiveness of PMHS using enquirer satisfaction surveys (e.g., (1, 2)). Until now, a review of the literature had not been conducted to bring together the available evidence as to the effectiveness of PMHS, nor has the quality of this evidence been examined.

In many countries, MI services are provided for the general public, rather than primarily for patients of a specific hospital (from here, medicines information services for the general public will be referred to as MISGP). Therefore, MISGP are available for patients and also the wider community, and their aim is typically to provide information and support for any medication. Their remit differs to that of PMHS, which specifically function to provide information and support regarding medication pertaining to a recent period of hospital care. Although this doctoral research focuses upon PMHS, MISGP were also included in this systematic review for two main reasons. First, in the UK there is currently a move towards optimising resources whereby healthcare services within regions aim for increased collaboration and coordination of services in order to improve efficiency (3, 4). Additionally, Study 1 found that the most cited reason for the lack of a PMHS in 48% of NHS Trusts in England is lack of resources. Study 1 concludes that further research is needed to explore the best way to support all patients who need help with their medicines following hospital discharge, which is cost-effective without diminishing quality. One option could be to adopt the model of MI provision for the general public (including patients) that is used in many countries outside of England (i.e., MISGP). Therefore, including the evidence pertaining to the effectiveness of both types of service would be useful for ascertaining whether the provision of MI services regionally may be a viable alternative to the provision of MI services from

all NHS Trusts. Second, since most MISGP are provided by countries outside of the UK, the inclusion of this literature would likely appeal to an international readership.

The aim of this study was to systematically review the literature pertaining to the effectiveness of medicines information services for patients (i.e., PMHS) and for the public (i.e., MISGP). In order to achieve this, the following research question was to be addressed: *What is the available evidence regarding the effectiveness of patient medicines helpline services and medicines information services for the general public?*

This systematic review focussed solely upon the 'effectiveness' aspect of the RE-AIM framework. Including all five dimensions of the RE-AIM framework within this systematic review was unnecessary, because the most recent findings pertaining to the adoption, reach, implementation, and maintenance of PMHS were reported in Study 1. Additionally, covering all aspects of RE-AIM within one systematic review was considered too broad, and with so much extant evidence pertaining to the effectiveness of MI services, this topic alone felt to be of sufficient scope.

To accord with the mixed methods approach of this doctoral research, any type of study design was included in this systematic review (e.g., qualitative, quantitative, or mixed), as long as the study met our eligibility criteria.

This study was published in the International Journal of Pharmacy Practice in 2019. Therefore, the published article is presented. Following the article is a brief summary of the study's findings, and a description of how the study fits within the wider context of the PhD.

5.2 Statement of authorship

This declaration concerns the article entitled:			
A systematic review examining the effectiveness of medicines information services for patients and the general public.			
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** √			
Publication details (reference)	Williams M, Jordan A, Scott J, Jones MD. A systematic review examining the effectiveness of medicines information services for patients and the general public. International Journal of Pharmacy Practice. 2019 Sep 12.		
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Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… *Formulation of ideas*: I formulated the ideas for this study (90%), with support from my supervisory team (10%). *Design of methodology*: I designed the methodology for this study (90%), with support from my supervisory team (10%). *Experimental work*: I carried out the study (i.e., collected and analysed the data) (100%). *Presentation of data in journal format*: I wrote the study for publication (85%), with support from my supervisory team (15%).		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	05/03/2020

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Expected size (number of pages)	500
Requestor Location	University of Bath University of Bath Bath, BA1 United Kingdom Attn: University of Bath
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The published article represents pages 80 to 94 of this thesis (15 pages).

Table 1 in the published article represents Table 5.1 of this thesis.
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Table 3 in the published article represents Table 5.3 of this thesis.
Table 4 in the published article represents Table 5.4 of this thesis.

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Appendix S1 in the published article represents Appendix 2 of this thesis.
Appendix S2 in the published article represents Appendix 3 of this thesis.
Appendix S3 in the published article represents Appendix 4 of this thesis.
Appendix S4 in the published article represents Appendix 5 of this thesis.

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IJPP International Journal of Pharmacy Practice

Review Article

International Journal of Pharmacy Practice 2019, ••, pp. ••–••

A systematic review examining the effectiveness of medicines information services for patients and the general public

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Keywords
drug information; drug information centre; hospital pharmacy; medicines information; patient medicines helpline; systematic review

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Received April 25, 2019
Accepted July 11, 2019

doi: 10.1111/ijpp.12571

Registration: PROSPERO CRD42017075165

Abstract

Objectives Hospital-based patient medicines helpline services (PMHS) and medicines information services for the general public (MISGP) are available in many countries to support people with their medicines. Our aim was to examine the available evidence regarding the effectiveness of PMHS and MISGP.

Methods Searches were conducted using Medline, EMBASE, CINAHL, Scopus and Web of Science, on 11 August 2018. Forward and backward citation searches were conducted, grey literature was searched, and study quality/risk of bias was assessed. Findings were synthesised in a narrative synthesis. Where appropriate, weighted means were calculated.

Key findings Thirty-two studies were identified for inclusion (17 published articles, 15 conference abstracts). Eighteen studies were conducted within the United Kingdom. Mean quality assessment was moderate (51%), and risk of bias was high (63%). PMHS and MISGP are both typically perceived as positive (e.g. 94% and 91% of participants were satisfied with using a PMHS and MISGP, respectively). For PMHS, the advice received is reported to be usually followed (94%, and 66% for MISGP). For both services, users report several positive outcomes (e.g. problems resolved/avoided, feeling reassured and improved health). PMHS may also be effective for correcting medicines-related errors (up to 39% of calls may concern such errors) and for potentially avoiding medicines-related harm (48% of enquiries concerned situations that were judged to have the potential to harm patients).

Conclusions Findings suggest that both PMHS and MISGP may be beneficial sources of medicines-related support. However, the moderate quality and high risk of bias of studies highlight that more high-quality research is needed.

Introduction

Prescription and over-the-counter medications are both fundamental and commonplace components of healthcare worldwide. For example, approximately half of people in both the United Kingdom and the United States of America take at least one prescribed medication on a regular basis.[1,2] Additionally, the use of medications is increasing. In the UK, there was a 65% increase in the annual number of prescriptions dispensed between 1999 and 2009, from approximately 653 million to 1074 million.[3,4]

A growing number of studies suggest that patients have a need for information and support regarding their medicines. Approximately 40% of patients who have been discharged from hospital may subsequently experience medicines-related problems, including medicines-related errors.[5–13] Findings indicate that patients often lack knowledge about their medications following hospital discharge[14–18] and that many patients report not receiving important medicines-related information.[19–21] World Health Organisation policy states that offering information on medicines via Medicines Information Centres, and providing public education about medicines, are two of 12 essential interventions to promote the

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rational use of medicines.[22] Therefore, medicines information (MI) services have been established in many countries to support patients and the general public with their medicines.

Patient medicines helpline services

In the UK, patient medicines helpline services (PMHS) are available for patients who have received care within some secondary healthcare settings.[23] The primary function of a PMHS is to enable discharged patients to communicate with a pharmacy professional from the healthcare setting where they recently received care. PMHS are therefore means of providing medicines-related support following hospital discharge. The first PMHS was established in the UK in 1992,[24] and a survey conducted in 2017 found that 52% of NHS Trusts[1] in England provide a PMHS.[23]

Although PMHS were initially set up to improve patients' knowledge and use of their medicines, recent guidelines for their implementation have suggested other benefits, for both service users and healthcare organisations.[25] Additional benefits include reducing harm to patients, highlighting and correcting medicine-related errors, reducing unnecessary use of other healthcare services, and improving the patient experience of healthcare services. While useful, the list of proposed benefits is not currently evidence-based, which is likely to limit their impact.

Medicines information services for the general public

In many countries, MI services are provided for the general public, rather than primarily for patients of a specific hospital (from here, MI services for the general public will be referred to as MISGP). Therefore, MISGP are available for patients and also the wider community, and their aim is typically to provide information and support for any medication. Their remit therefore differs to that of PMHS, which specifically function to provide information and support regarding medication pertaining to a recent period of hospital care. MISGP are often provided from Drug Information (DI) Centres or Drug and Poison Information Centres that are often regional or national in scope rather than local to specific hospitals.[26–32] Additionally, the general public in some non-UK countries such as the United States may also have the option of acquiring MI from services that provide alternative communication methods to telephone helplines, such as online 'Ask-the-Pharmacist' services.[33–35]

Aim

To date, a review of the literature has not been conducted which brings together the available evidence as to the effectiveness of either PMHS or MISGP, nor the quality of the evidence. The aim of this systematic review was to answer the following research question: *What is the available evidence regarding the effectiveness of PMHS and MISGP?*

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[36] was used in the planning, conducting and reporting of this systematic review. The PRISMA statement protocol counterpart (PRISMA-P)[37] was used to develop the protocol for this review. The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 10 October 2017 (registration number CRD42017075165).[38]

Eligibility criteria

Studies were included in this systematic review if they used any design in order to examine any outcomes for service users, service providers, and/or healthcare organisations, pertaining to the effectiveness of PMHS and/or MISGP. Service users' perceptions of the value of MI services were included as a type of effectiveness, since UK policies emphasise the importance of the patient experience, that the NHS is committed to patient involvement in healthcare, and that services should be shaped around patients' needs.[39–41]

For the purpose of this systematic review, PMHS and MISGP were considered to have the following characteristics:

(1) A service involving any type of distance communication between the service user and service provider, instigated by the service user.
(2) A service primarily providing MI, and not general clinical information and advice. The service could cater for enquiries about prescribed medicines and/or over-the-counter medicines. However, services that function to predominantly answer enquiries about the following were excluded: complementary and alternative medicines, illicit drugs, and poisonings. Additionally, telepharmacy and e-pharmacy services typically provide a general pharmacy service rather than an MI service, albeit remotely.[42] Therefore, we excluded studies that examined telepharmacy services and/or e-pharmacy services. Services that provide MI for both healthcare professionals and patients/public were also

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considered. However, studies were only included if relevant findings for patients/public were separately reported to the findings for healthcare professionals.

(3) A service that operated from any setting, within any country.

(4) A service available over a sustained period of time. Therefore, we excluded studies that examined services that were available for a limited time only (e.g. a medicine phone-in day).

(5) For PMHS: a service for patients and/or carers of patients who received care from the healthcare organisation that provides the helpline. For MISGP: a service for the general public of a region or nation.

We included published studies (including published theses), unpublished studies, abstracts and conference proceedings that were written in English. Abstracts and conference proceedings were only included if there was sufficient reporting of method and results to meet our study objectives. We included articles written in non-English languages where the abstract was reported in the English language, if the abstract alone provided information to support our research objectives. We excluded studies if the data were presented in a subsequently published format (e.g. we excluded a study in a conference proceeding if it was subsequently published as a full-text article). No restriction was made regarding year of publication.

Search strategy

Searches were conducted using Medline, EMBASE, CINAHL, Scopus and Web of Science (Science Citation Index Expanded, Social Science Citation Index, Conference Proceedings Citation Index – Science, Conference Proceedings Citation Index – Social Science & Humanities, Emerging Sources Citation Index). Where possible, searches were conducted using both free-text and subject headings. Search terms and the search strategy were determined for EMBASE and subsequently adapted to the syntax and subject headings of the other databases (see Appendix S1 for the EMBASE search strategy). Searches were conducted on 1 August 2017 and updated on 11 August 2018. Forward and backward citation searches were conducted for all included studies. Forward citation searches were conducted on 11 August 2018, using Scopus, Web of Science and Google Scholar.

The following grey literature sources were searched: grey literature databases (OpenGrey, and ProQuest database for dissertations and theses), Google and Google Scholar, conference proceedings, and consultation with experts (see Appendix S2 for further details).

Screening and selection of studies

Literature search results for all databases were exported to Covidence,[43] duplicates were removed, and studies were screened and selected. Two researchers independently screened all titles and abstracts for relevance, and disagreements were resolved by discussion. Articles that met the inclusion criteria, or where there was any uncertainty, were obtained in complete form. Full-text reports were then independently examined against the inclusion criteria by one researcher, who examined them all, and two postgraduate researchers from the University of Bath, who each examined 50%. Any remaining disagreements were resolved by discussion between two researchers.

Data extraction

Data extraction was conducted by one researcher using a data extraction form, with 20% verified by another researcher (see Appendix S3 for the data extraction form). No discrepancies were found. Details from all data extraction forms were subsequently entered into an Excel spreadsheet in preparation for analysis. Raw data were not analysed for this systematic review. However, where there was the potential to obtain data in a more relevant format, authors of studies were contacted.

Quality assessment of included studies

The AXIS tool[44] was chosen to assess both risk of bias and quality, for the purpose of information and synthesis, and not to exclude studies from this systematic review. The AXIS tool comprises 20 items, most of which were relevant for the descriptive cross-sectional studies likely to comprise the majority of studies in this systematic review. Different study designs have the potential for different biases, and the three main potential biases in cross-sectional and descriptive studies pertain to the proper selection of the sample (selection bias), the soundness of outcome measurement (measurement bias), and the selective reporting of findings (reporting bias).[45–48] The AXIS tool comprises subscales for separately measuring risk of bias, quality of reporting, and quality of study design. The risk of bias items allow for the measurement of selection bias, measurement bias, and reporting bias.

Each included study, for which there was a full report of the study that was written in English, was independently appraised for quality by two researchers. Only full reports were appraised, since they contained enough information to adequately assess the risk of bias and the quality of reporting. Disagreements were resolved through discussion between two researchers.

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Narrative synthesis

Findings were synthesised in a narrative synthesis around the study objectives. The narrative synthesis was undertaken based upon the guidelines of Popay *et al.*[49] Due to heterogeneity in the services evaluated and the research methodologies employed, meta-analysis was not considered appropriate. However, where relevant, weighted averages were calculated across studies to account for the potential impact of varying sample sizes.

Results

Study selection

A total of 32 studies were identified for inclusion in this review. Figure 1 shows a flow diagram of the study selection process.

Study characteristics

All of the included studies are summarised in Table 1. Of the 32 included studies, 17 studies contained data that examined a MISGP (53%) and 15 studies contained data that examined a PMHS (47%). Seventeen were published studies in peer-reviewed journals (53%), and 15 were conference abstracts (47%).

Of the 32 studies, 18 were evaluating services in the UK (56%), six were evaluating services in North America (19%), five were evaluating services in other countries within Europe (16%), and three were evaluating services in other areas of the world (9%).

Four study designs have been used to examine the effectiveness of PMHS and MISGP: cross-sectional surveys of service users (27 studies; 84%), retrospective reviews of enquiries (seven studies; 22%), retrospective reviews of answers using expert panels (four studies; 13%) and cross-sectional surveys of service providers (one study; 3%). Six studies had more than one design (19%).

Quality assessment and risk of bias within studies

Sixteen studies met our criteria for quality and risk of bias assessment (i.e. a full report, written in English). Fleiss Kappa was conducted, showing that there was substantial agreement between raters[50], $K = 0.63$ (95% CI, 0.53 to 0.73), $P = 0.000$.

The mean percentage for overall quality for the 16 assessed studies was 51% (range = 25–95%). For the *Risk*

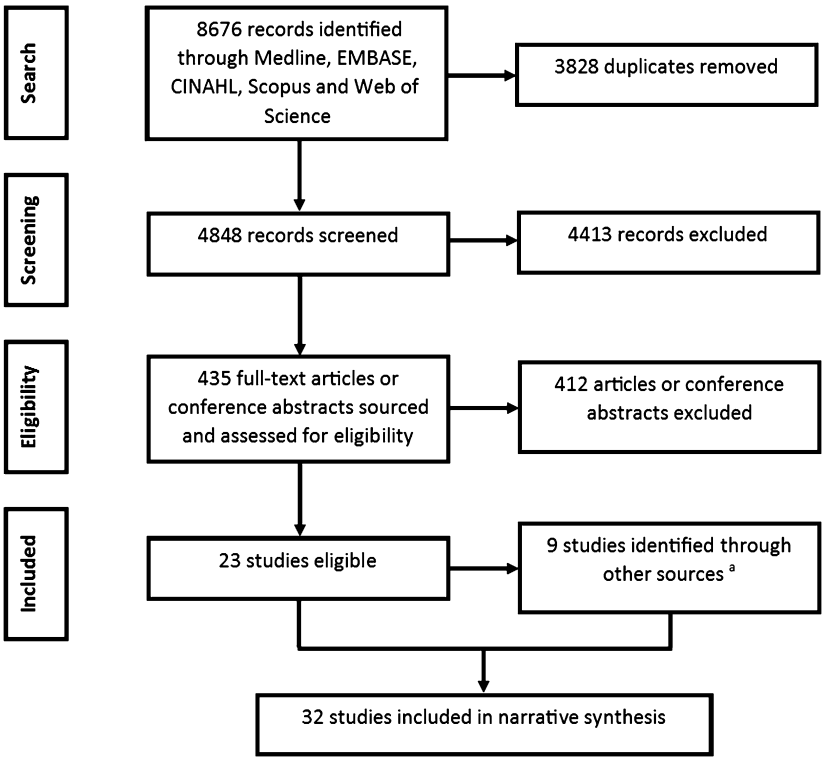

Figure 1 Flow diagram of the study selection process.

[a]Forward and backward citation searches, grey literature databases (OpenGrey and ProQuest database for dissertations and theses), Google and Google Scholar, targeted websites/sources and consultation with experts.

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Table 1 Studies meeting the eligibility criteria for the systematic review examining medicines information services for patients and the general public

First author, year	Publication status	Study design/s	Service type	Country	Sample size
Alomi, 2015 [51]	CA	RRE	MISGP	Saudi Arabia	NR
Ansani, 2006 [52]	PS-PR	SSU	MISGP	USA	6 respondents
Badiani, 2017 [53]	PS-PR	RRE; SSU	PMHS	England	637 enquiries; 100 respondents
Barker, 2016 [54]	CA	SSU	PMHS	England	9 respondents
Blom, 1991 [55]	PS-PR	SSU	MISGP	Netherlands	200 respondents
Bramley, 2012 [56]	CA	SSU	PMHS	England	73 respondents
Bramley, 2014 [57]	PS-PR	RRE	PMHS	England	312 enquiries
Bramley, 2014 [58]	CA	SSU	PMHS	England	17 respondents
Bramley, 2015 [59]	CA	SSU	PMHS	England	97 respondents
Bramley, 2018 [60]	PS-PR	RRA-EP; SSU	PMHS	England	67 respondents
Conner, 1980 [61]	PS-PR	SSU	MISGP	USA	73 respondents
Conner, 1982 [62]	PS-PR	SSU	MISGP	USA	793 respondents
Cuthbert, 2013 [63]	CA	RRE; RRA-EP; SSU	PMHS	Scotland	18 enquiries; 17 respondents
Goltz, 2009 [64]	CA	SSU	MISGP	Germany	151 respondents
Goltz, 2011 [65]	CA	SSU	MISGP	Germany	496 respondents
Heaton, 2018 [66]	CA	SSU	PMHS	England	20 respondents
Jones, 2014 [67]	CA	RRE; SSU	PMHS	England	234 enquiries; 68 respondents
Joseph, 2004 [68]	PS-PR	SSU	PMHS	England	58 respondents
Law, 2015 [69]	CA	RRE	PMHS	England	109 enquiries
Markovits, 2011 [70]	CA	SSU	MISGP	Israel	30 respondents
Marvin, 2011 [71]	PS-PR	RRE	PMHS	England	500 enquiries
Maywald, 2004 [72]	PS-PR	SSU	MISGP	Germany	920 respondents
McCartan, 2016 [73]	CA	SSU	PMHS	Northern Ireland	14 respondents
Melnyk, 2000 [74]	PS-PR	SSU	MISGP	Canada	99 respondents
Melnyk, 2000 [75]	PS-PR	RRA-EP; SSU	MISGP	Canada	68 enquiries; 64 respondents
Muhammad, 1998 [76]	PS-PR	SSU	MISGP	England	57 respondents
Olofinjana, 2009 [77]	PS-PR	SSU	MISGP	UK	123 respondents
Raccah, 2011 [78]	CA	SSU	MISGP	Israel	268 respondents
Rhodes, 2017 [79]	CA	RRA-EP; SSU	MISGP	France	200 enquiries; 149 respondents
Rutter, 2012 [80]	PS-PR	SSU	MISGP	UK	77 respondents
Smith, 1985 [81]	PS-PR	SSU	MISGP	USA	154 respondents
Williams, 2018 [23]	PS-PR	SSP	PMHS	England	156 respondents

All studies evaluated services that were accessed via telephone, except the service evaluated by Ansani *et al*., which was accessed online.
General abbreviations: MISGP, medicines information service for the general public; NR, not reported; PMHS, patient medicines helpline service. 'Publication status' abbreviations: CA, conference abstract; PS-PR, published study in a peer-reviewed journal. 'Study design' abbreviations: RRE, retrospective review of enquiries; RRA-EP, retrospective review of answers by expert panel; SSP, cross-sectional survey of service providers; SSU, cross-sectional survey of service users.

of Bias subscale, the mean percentage for risk of bias across the studies was 63% (range = 17–100%). For the *Quality of Reporting* subscale, the mean percentage across the studies was 59% (range = 14–100%). For the *Quality of Study Design* subscale, the mean percentage across the studies was 55% (range = 29–100%) (See Appendix S4 for the overall scores and percentages of quality and risk of bias for all 16 studies).

Effectiveness of PMHS and MISGP

Service users' perceptions of using a PMHS or MISGP

Twenty-two studies examined services users' perceptions of using PMHS and MISGP, using self-report survey methods. Twelve studies examined a MISGP and 10 examined a PMHS. Nineteen outcomes were reported, and are presented in Table 2. More outcomes were reported for PMHS than for MISGP (14 and 11, respectively). Most outcomes were reported by a high percentage of enquirers (typically, 90% and above).

Two studies reported negative feedback from survey respondents.[59,60] Bramley and Hollamby[59] surveyed 97 patients who used one of several PMHS in London between 2011 and 2013. Negative feedback reported by service users were as follows: being provided with insufficient information; feeling that they did not gain anything from calling the helpline, since they were referred to their GP; being told to contact another person, which prolonged the process; and being advised with unclear language. However, the authors did not report actual

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Table 2 Services users' perceptions of using medicines information services for patients and the general public

Outcome	Patient medicines helpline services			Medicines information services for the general public		
	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)
Felt understood	4 [53,54,56,60]	99–100% (100%)	9–100 (249)	0	N/A	N/A
Would use the service again	5 [53,54,58,60,66]	94–100% (98%; 98%)	9–100 (213)	2 [52,55]	83–93% (88%; 93%)	6–200 (206)
Able to understand the information/advice	2 [56,60]	97–100% (99%; 98%)	67–73 (140)	0	N/A	N/A
Felt confident in the answer provided	3 [53,54,73]	98–100% (99%; 98%)	9–100 (123)	0	N/A	N/A
Overall experience of the hospital was improved	1 [67]	98%	68	0	N/A	N/A
The service was helpful[a]	6 [53,54,56,67,68,73]	88–100% (97%; 96%)	9–100 (322)	1 [81]	99%	154
Enough information was provided	2 [53,60]	93–98% (96%; 96%)	67–100 (167)	1 [80]	90%	77
The information was timely	3 [56,58,66]	76–100% (91%; 94%)	17–73 (110)	2 [74,75]	97–98% (98%; 97%)	64–99 (163)
Satisfied with the service[b]	2 [63,68]	92–100% (96%; 94%)	17–58 (75)	5 [55,64,72,77,80]	90–94% (92%; 91%)	77–920 (1471)
No improvements to the service considered necessary	2 [56,63]	88–94% (91%; 89%)	17–73 (90)	0	N/A	N/A
The service was useful[c]	1 [60]	88%	67	5 [52,65,74,76,79]	83–100% (92%; 92%)	6–496 (807)
Access to the service was easy	5 [53,54,60,68,73]	61–100% (88%; 85%)	9–100 (235)	0	N/A	N/A
The service was excellent	3 [53,54,60]	61–80% (73%; 73%)	9–100 (176)	0	N/A	N/A
Additional information was given	2 [56,63]	14–47% (31%; 20%)	17–73 (90)	0	N/A	N/A
The information provided was relevant	0	N/A	N/A	1 [79]	100%	149
Would recommend the service	0	N/A	N/A	2 [52,80]	83–100% (92%; 99%)	6–77 (83)
The advisors were competent	0	N/A	N/A	1 [72]	69%	920
The service was thorough	0	N/A	N/A	1 [72]	52%	920
Useful to be able to obtain a second opinion	0	N/A	N/A	1 [72]	40%	920

Twenty-two studies examined self-reported outcomes for enquirers of medicines information services. Therefore, some studies reported more than one type of outcome. Outcomes are listed according to the weighted mean percentage for studies that examined PMHS, from largest to smallest.

Abbreviations: N/A, no relevant data were found for these categories; WM, weighted mean (weighted by sample size).

[a]Due to different answer options being used across studies, for some studies 'helpful' and 'very helpful' were added together to produce the percentage of service users that found the service to be helpful.

[b]Due to different answer options being used across studies, for some studies 'satisfied' and 'very satisfied' were added together to produce the percentage of service users that were satisfied with the service.

[c]Due to different answer options being used across studies, for some studies 'useful' and 'very useful' were added together to produce the percentage of service users that found the service to be useful.

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percentages of participants who were affected by each of these issues.

Out of 67 service users surveyed by Bramley *et al.*,[60] 15% (n = 10) disclosed issues with the PMHS they used. Three patients reported that the helpline advisor could not answer their question, three patients were referred to somebody who could not help them, two patients said that they were not counselled on potential side effects, one patient felt confused by the advice, and one patient reported being given irrelevant advice.

Impact of using a PMHS or MISGP for service users

Service users' perceptions of the impact of using a PMHS or MISGP

Twenty-one studies examined service users' perceptions of the positive impact of using a PMHS or MISGP, using self-report survey methods. Eleven studies examined a MISGP, and 10 examined a PMHS. Sixteen outcomes were reported, and the findings are presented in Table 3. More outcomes were reported for PMHS than for MISGP (16 and eight, respectively).

Four studies reported whether there were negative outcomes for the patient/enquirer's health, well-being or symptoms that could be directly attributed to using the MI service. For PMHS, one study found that there were no reported negative effects.[73] Another study found that, out of 58 respondents, 6% reported some negative impact on social well-being and physical well-being, and 4% reported some negative impact on emotional well-being from using a PMHS.[68] Additionally, a quarter of their sample felt more anxious after using a PMHS (exact percentage not reported).[68] For MISGP, one study found that, out of 920 respondents, 1% reported poorer health,[72] and another study found that, out of 123 respondents, 5% reported that their condition was worse.[77]

Use of expert panels to examine the impact of PMHS and MISGP

Two studies included a design whereby an expert panel reviewed enquiries and answers provided by a PMHS.[60,63] In one of the studies, the expert panel comprised three independent experts in medicine, pharmacology and patient safety methodology,[63] and in the other study, the expert panel comprised 12 MI pharmacists.[60] For the two studies, the panels agreed that there was a potential positive impact on patient care or outcome in 74% and 89% of cases (n = 46/62 and n = 16/18, respectively) and that there was a potential positive impact on medication safety in 71% and 78% of cases (n = 44/62 and n = 14/18, respectively).

Two studies included a design whereby an expert panel reviewed enquiries and answers provided by a MISGP.[75,79] Melnyk *et al.*[75] used an expert panel (two clinical pharmacists and two physicians experienced in general medicine) to classify the potential impact on patient outcome of responses to 68 enquiries to a MISGP in Canada. None of the responses were considered to result in a negative outcome. There were 25 potential positive patient outcomes (37%). Of the queries that potentially resulted in a positive patient outcome, medication administration may have been optimised in 44% of cases, there may have been a reduction/elimination of symptoms in 44% of cases, and there may have been a prevention of disease/symptoms in 12% of cases.

Rhodes *et al.*[79] used an expert panel (membership not reported) to evaluate the perceived impact of 200 enquiries to a MISGP in France. They found that 81% of responses to enquiries were evaluated as potentially having a significant, very significant or vital impact (n = 162/200). The remaining 19% were evaluated as having no significant impact (n = 38/200).

Preventing harm from medicines

One study examined the potential for harm pertaining to the enquiries received by a PMHS.[71] This was achieved by coding 500 calls as to whether or not they pertained to harm (harm was defined as temporary or permanent impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom, requiring intervention). Findings identified that 48% of enquiries (n = 241) were regarding situations judged to have the potential for harm from the medicine/s in question. Of these, 1.7% were then categorised as Harm Index Category F (requiring intervention and referral), 19.9% were categorised as Harm Index Category E (temporary harm not requiring follow-up), and 78.4% were categorised as Harm Index Categories B–D (an error occurred, but did not cause harm). This suggests that PMHS have the potential to prevent medicines-related harm to patients. However, a limitation of this study is that only one researcher (expertise not reported) coded the enquiries.

Correcting medicines-related errors

Six studies reported data from retrospective reviews of enquiries to PMHS, to establish the percentage that were regarding medication errors.[53,57,63,67,69,71] Combined, the studies found that between 8% and 39% of calls to PMHS

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Table 3 Services users' perceptions of the impact of using medicines information services for patients and the general public

Outcome	Patient medicines helpline services			Medicines information services for the general public		
	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)
Recommendations were followed	5 [56,60,63,67,68]	88–100% (93%; 94%)	18–73 (284)	3 [61,70,72]	63–96% (79%; 66%)	73–920 (1073)
A benefit was experienced (unspecified)	1 [60]	86%	62	2 [64,75]	89–92% (91%; 90%)	64–151 (215)
An issue/problem was resolved	5 [53,54,66,67,73]	33–100% (65%; 66%)	9–100 (211)	1 [62]	74%	793
Felt reassured or less anxious	9 [53,54,56,58,60,63,67,68,73]	38–100% (67%; 65%)	9–100 (423)	2 [55,77]	11–29% (20%; 22%)	123–200 (323)
Felt more confident taking medicines	1 [58]	65%	17	4 [64,65,72,78]	66–72% (69%; 69%)	151–920 (1835)
Had increased knowledge/understanding of medicines	5 [56,58,60,63,67]a	31–82% (63%; 55%)	17–73 (229)	2 [55,76]	49–88% (69%; 58%)	57–200 (257)
Believed that harm was avoided	2 [56,63]	43–59% (51%; 46%)	17–73 (90)	0	N/A	N/A
The information provided was used to make a decision about medicines	1 [60]	43%	54	0	N/A	N/A
The patient was able to start taking their medicines	1 [73]	43%	14	0	N/A	N/A
A problem was avoided	3 [53,68,73]	21–67% (38%; 40%)	14–100 (172)	0	N/A	N/A
There was an improvement in health, well-being, or symptoms	6 [56,60,63,67,68,73]	7–83% (34%; 34%)	14–73 (292)	2 [72,77]	20–42% (31%; 23%)	123–920 (1043)
Treatment was changed as a result of using the service	5 [56,60,63,67,73]	13–53% (29%; 27%)	14–73 (231)	2 [77,78]	41–47% (44%; 43%)	123–268 (391)
The patient changed or improved the way they take their medicines	3 [58,67,73]	6–76% (34%; 27%)	14–68 (99)	0	N/A	N/A
The patient was more likely to take their medicines regularly	2 [58,67]	6–53% (30%; 15%)	17–68 (85)	0	N/A	N/A
The patient was less likely to miss a dose	2 [58,60]	4–41% (23%; 13%)	17–54 (71)	0	N/A	N/A
The patient was able to obtain a supply of their medicines	2 [67,73]	10–12% (11%; 10%)	14–68 (82)	0	N/A	N/A

Twenty-one studies examined self-reported outcomes for enquirers of medicines information services. Therefore, some studies reported more than one type of outcome. Outcomes are listed according to the weighted mean percentage for studies that examined PMHS, from largest to smallest.

Abbreviations: N/A, no relevant data were found for these categories; WM, weighted mean percentage (weighted by sample size).

[a]Jones *et al*.[80] provided additional detail about the type of knowledge that was increased. Thirty-one per cent reported an increased understanding of interactions; 18% reported an increased understanding of side effects and safety; 15% reported an increased understanding of how to take their medicines; and 9% reported an increased understanding of supplies, changes to their medicines, and indications.

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Table 4 Services users' suggested sources of support from healthcare professionals/services had their medicines information service not been available

Healthcare service/professional contacted if MI service was not available	Patient medicines helpline services			Medicines information services for the general public		
	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)	No. studies examining outcome	Range of % (mean; WM)	Range of *N* (total *N*)
GP	2 [67,73]	36–65% (51%; 41%)	14–68 (82)	4 [55,76,77,81]	15–58% (40%; 38%)	57–200 (534)
Hospital where they received care	2 [67,73]	29–31% (30%; 29%)	14–68 (82)	1 [76]	6%	57
Pharmacist	2 [67,73]	7–40% (24%; 13%)	14–68 (82)	4 [55,76,77,81]	10–62% (31%; 34%)	57–200 (534)
Other healthcare professional/service	1 [67][a]	10%	68	2 [77,81]	8–11% (10%; 9%)	123–154 (277)
Would go without help	2 [67,73]	3–14% (9%; 5%)	14–68 (82)	3 [55,76,81]	12–23% (16%; 17%)	57–200 (411)
Nurse	0	N/A	N/A	2 [76,81]	2–10% (6%; 8%)	57–154 (211)

Six studies examined the healthcare service/professional most likely contacted had the MI service not been available. Therefore, some studies reported more than one healthcare service/professional. Outcomes are listed according to the weighted mean percentage for studies that examined PMHS, from largest to smallest.

Abbreviations: GP, general practitioner; MI, medicines information; N/A, no relevant data were found for these categories; WM, weighted mean percentage (weighted by sample size).

[a]The 'other healthcare professional/service' reported in this study was NHS 111, a national medical helpline in England.

concerned errors (mean = 26%; weighted mean = 28%). This suggests that correcting errors is an important function of PMHS. However, it is unknown whether different definitions of an error were used across the studies, which may have influenced the results. Additionally, one study reported that only one researcher coded the enquiries,[71] and the remaining five studies did not report the number of coders used.

Reducing the burden upon other healthcare services

Six studies reported the percentages of service users who would use alternative healthcare professionals/services had the MI service not been available; two examining PMHS[67,73] and four examining MISGP.[55,76,77,81] The findings are presented in Table 4. Additionally, out of 920 respondents, Maywald *et al.*[72] found that 18% of callers to a MISGP in Germany (n = 168) believed that the advice they received prevented a visit to their physician.

Economic impact

Two studies explored the economic impact of MISGP. Both studies were available as conference abstracts only, therefore their descriptions were limited.

Alomi *et al.*[51] sought to establish the cost-efficiency of a national MISGP in Saudi Arabia. They analysed all calls received to the service during 2014 and predicted the cost for each situation pertaining to the enquiries, had the service not been available. They estimated that the cost avoidance of answering public enquiries for one year was $80 806. However, they did not provide details as to how this was assessed.

Rhodes *et al.*[79] conducted an analysis of 200 calls received in 2016 to a national MISGP in France. Using an expert panel, they concluded that 25% of calls to the service had an economic impact, although they do not report what impact, nor the monetary value of the impact.

Service providers' opinions as to the effectiveness of their service

Williams *et al.*[23] surveyed pharmacy professionals (MI Pharmacists and Chief Pharmacists) in 2017 for their perceptions regarding the major benefits of their PMHS. The top 10 perceived benefits were as follows: avoiding harm to patients (88%; n = 137/156), improving patient medication adherence (85%; n = 133/156), providing assurance to patients that they can access professional help from home (83%; n = 129/156), improving the patient

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experience (80%; $n = 125/156$), supporting patient discharge (76%; $n = 119/156$), optimising medicines (75%; $n = 117/156$), identifying errors (75%; $n = 117/156$), reducing medicines-related readmissions (65%; $n = 101/156$), learning from adverse patient experiences (55%; $n = 86/156$) and reducing visits to other healthcare services (51%; $n = 80/156$). However, a limitation of this study as a measure of effectiveness is that it relied upon the perceptions of service providers rather than a direct measure. Results also may be biased if participants were apprehensive about reporting any negative or poor aspects of their service.

DISCUSSION

This systematic review examined the available evidence regarding the effectiveness of MI services for patients and the general public. The evidence suggests that both PMHS and MISGP may help to increase service users' knowledge, understanding and use of their medicines, and that advice is typically reported as being followed. Both PMHS and MISGP are typically perceived as positive by service users (e.g. satisfaction ratings are typically very high), and service users may report several positive outcomes attributed to using them, such as problems being resolved or avoided, and experiencing improvements to their health.

Studies also suggest that both PMHS and MISGP may have an impact upon other healthcare services, such as reducing the burden upon primary care (i.e. if the helpline did not exist, respondents report that they would likely contact their GP instead; weighted mean for PMHS = 41%; weighted mean for MISGP = 38%). This is topical, given that the average waiting time from booking a standard appointment to see a GP in England in 2016 and 2017 was estimated to be approximately 2 weeks.[82] This suggests that, by increasing patients' and carers' awareness of MI services that are available to them, patients can receive support much sooner than if they book an appointment to see their GP, and GP time will be less taken up with answering MI queries that may be more appropriately dealt with via MI pharmacists.

Although a larger number of studies have been conducted to examine a MISGP compared with a PMHS, more outcomes have been reported for PMHS than for MISGP. Of those outcomes reported for both service types, some outcomes are superior for PMHS whereas other outcomes are superior for MISGP. However, it is not legitimate to draw comparisons between the effectiveness of the two service types based upon the available evidence in this review, since no evidence was found that compared the two service types within the same study. Additionally, a comparison between the two service types may be inappropriate, since their functions are not exactly the same. A recent study by Badiani *et al.*[53] found that, out of 200 enquiries to their PMHS, 75% required access to hospital-based resources (e.g. patients' electronic medical records, and contacting a healthcare professional involved in the patient's care). Badiani *et al.* conclude that their findings support the value of hospitals providing a PMHS for their own patients, rather than having a smaller number of centralised MI services for all individuals within a region. It may be that MISGP are suitable for more general enquiries that do not require access to a patients' record (e.g. enquiries pertaining to over-the-counter medicines), whereas PMHS may be more suitable for more complex enquiries pertaining to medicines specifically prescribed from the hospital where the enquirer recently received care. Future research could aim to establish this by examining the types of enquiries made to the two different services. Due to their different functions, it may be that providing patients and the general public with both PMHS and MISGP is useful for supporting them regarding all types of medicines-related queries.

A potential strength of the available evidence is that several different study designs have been used to examine the effectiveness of MI services, including retrospective reviews of enquiries, use of expert panels, and cross-sectional surveys with service users and service providers. However, the use of a variety of study designs can only be considered a strength if the studies themselves are methodologically robust and of a high quality. We found that the overall quality of the evidence was moderate (on average, 51%), and there was a high risk of bias (on average, 63%). Most of the included studies were service evaluations whereby study authors had evaluated their own service. Additionally, evidence was primarily based upon self-report methods, and such findings may be subject to bias since service users' perceptions of impact may not be the same as actual impact. A small number of studies have also been conducted using expert panels, and these also report PMHS and MISGP to have a positive impact on patient outcomes. However, expert panels require expertise in judging both the nature of the enquiry and the appropriateness of the response in the context in which it is made, and such details were not always explicitly reported in the included studies. This review highlights the need for more high-quality research to adequately evaluate the impact of these services.

Recommendations

Practice

The evidence from this review shows that PMHS and MISGP may have a number of benefits for service users and healthcare organisations. Healthcare organisations

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that currently do not provide an MI service to patients and/or the public should consider whether the evidence is sufficient to merit developing their own.

We encourage MI service providers to evaluate the types of enquiries they receive by using standardised categories and coding instructions/training (e.g. those that were developed by the UK Medicines Information network; UKMi). This will enable the types of enquiries to be more appropriately compared across sites and regions within a country and across countries. Relatedly, the wide variety in error rates found across studies in this review (i.e. 8–39%) may reflect the use of different definitions as to what constitutes a medicines-related error, since the definition of an error has been found to have an effect upon rates.[83,84] We therefore also recommend that sites use a standardised definition of 'medicines-related error', including a standardised categorisation/coding scheme for collecting and analysing enquiry data.

Future research

Further research is needed to examine the effectiveness of both PMHS and MISGP (both in the UK and internationally), and we encourage researchers to use the findings from this review to design and conduct high-quality studies that fill gaps in the evidence base for both types of service.

In the UK, the UKMi provide an example survey to collect feedback regarding service users' experiences of using PMHS.[25] This tool was used in several of the studies included in this review. However, the psychometric properties of the tool have not been evaluated, and its reliance upon checkboxes may produce misleading results. It would therefore be beneficial for a psychometrically robust survey tool to be developed in order to more adequately examine service users' perspectives regarding the effectiveness of PMHS and MISGP.

The evidence in this review is compiled predominantly from studies conducted by sites that have examined their own service, which may not be generalizable and are at a high risk of bias. For both types of services, independently conducted, larger and higher-quality multi-centre studies are needed to examine their effectiveness. Relatedly, the average response rate for cross-sectional surveys completed by service users in this review was 55%, and reported response rates were often calculated based upon the number of responses received out of the total number of callers *who were asked* and who agreed to participate. Therefore, it is questionable as to whether the positive findings regarding the effectiveness of PMHS and MISGP are generalizable if, for example, those who had a negative experience chose not to respond or were not asked to participate in the first place. Future research could seek to improve the generalizability of survey studies by inviting *all* callers during the recruitment phase of the study. Examples of ways to improve response rates include offering an incentive, providing respondents with different modes of completing the survey (i.e. postal and online) and by resending the survey to non-responders.[85]

Only six of the 32 studies that examined the effectiveness of PMHS and MISGP provided data regarding perceived negative opinions/outcomes of the service. One study found that a quarter of service users felt more anxious after using a PMHS, although the study authors did not explore reasons for these findings.[68] Therefore, further research could seek to examine both positive and negative aspects of service users' experiences. For example, qualitative interviews with service users could be beneficial for exploring in greater depth the experiences of patients and the general public regarding their use of a PMHS or a MISGP. This could help to understand why some callers report feeling more anxious after using a PMHS, and potentially detect other adverse effects that may not be captured in surveys. Qualitative methods would also be useful for establishing what patients and the general public want from an MI service, and whether there are specific ways that PMHS and MISGP could be improved to better suit their needs.

Future research could also examine whether PMHS and MISGP have the potential to reduce hospital readmission rates, and the extent that the reduced burden upon other healthcare services (e.g. emergency departments and primary care services) translates into cost savings. Two studies sought to examine the cost-efficiency of MISGP. However, the available evidence was limited, since the studies were conference abstracts. Such findings could help support sustainable funding models, thus improving the adoption and maintenance of MI services for patients and the general public.[86]

Strengths and limitations

This is the first systematic review that has examined the effectiveness of MI services for patients and the general public. We have identified, synthesised and appraised a large body of evidence regarding MI services for both patients and the general public from countries worldwide. This has resulted in our development of recommendations to improve current practice in the operation of MI services, and for areas for future research.

One limitation of this systematic review is that the tool selected to assess the quality and risk of bias of studies was new, and consequently, its psychometric properties had not been evaluated.[44] This may have affected the inter-rater agreement that was conducted for this review. However, we found that our inter-rater agreement was

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satisfactory.[87] Additionally, the issue of lack of psychometric evaluation was common to all of the tools we considered for use in this study to assess quality and risk of bias. Systematic reviews of tools for assessing quality and risk of bias have concluded that there is no single obvious candidate tool for assessing the risk of bias or quality in cross-sectional studies.[88–90]

Relatedly, only 16 of the 32 studies in this review met our eligibility criteria for the assessment of quality and risk of bias, since most studies were from conference abstracts. Of the 16 studies, on average, their quality was found to be moderate (51%; range = 25–95%) and their risk of bias was found to be high (63%; range = 17–100%). Therefore, the findings may be limited due to the lack of high-quality studies currently available.

Another limitation of this review is that we only included articles written in non-English languages where the abstract was reported in the English language, if the abstract alone provided information to support our research objectives. Therefore, it may be that some relevant articles were excluded from this review. However, the maximum number of articles that this could have applied to was six (out of 8676). Additionally, the search for studies for this review was conducted in August 2018. It is possible that other studies may have subsequently been published which could affect the overall findings.

Finally, this systematic review combined the results for MISGP across countries (e.g. USA, Canada, Germany, France, Netherlands, Israel, Saudi Arabia). It is possible that differences may exist regarding the provision of MISGP by each of these countries, which may have affected the pooled findings in our review. However, the aim of our review was to provide an overview of the effectiveness of MISGP as a starting point for future research to build upon.

Conclusions

This systematic review provides evidence to suggest that PMHS and MISGP may be beneficial sources of support for recently discharged hospital patients and the general public, respectively. Overall, the quality of the included studies was found to be moderate, and there was a high risk of bias in the studies. Most studies were service evaluations conducted by the providers of their own service. Therefore, more high-quality research is needed to build the evidence base regarding the effectiveness of both types of services, ideally by researchers who are independent of the services being studied. This will enable healthcare commissioners and providers to be better informed to make decisions regarding robust MI service design and delivery.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

Funding

The lead author was funded by a Graduate School Scholarship provided by the University of Bath. The funder had no role in the study design, the collection, analysis and interpretation of the data, the writing of the report and the decision to submit the article for publication.

Acknowledgements

We would like to thank Danielle Cox and Tessa Rugg for their help with the screening and quality assessment stages of this review.

Ethics approval and consent to participate

Not applicable, since the research used secondary data sources collected from published and unpublished studies.

Consent for publication

Not applicable.

Data availability statement

Not applicable, since no primary data were collected or used for this research.

Note

[1] The National Health Service (NHS) in England is organised into NHS Trusts, which are organisations that provide goods and services for the purposes of health care (e.g. hospital and community services), and each Trust primarily serves a geographical area within England.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Search strategy for EMBASE.

Appendix S2. Grey literature search strategy.

Appendix S3. Data extraction form.

Appendix S4. Quality assessment and risk of bias table.

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5.5 Data access statement

As specified in the published article, no data are available, since no primary data were collected for this research.

5.6 Gaps in the evidence-base

In 2015, a small group of medicines information pharmacists compiled and published a list of proposed benefits of providing a PMHS (5). Table 5.5 presents these proposed benefits, whether the systematic review found any relevant evidence for each of the benefits, and if so, the type of data used to collect the evidence and the quality of the evidence.

This table highlights that there are gaps in the evidence-base regarding PMHS. For example, all conducted studies have collected quantitative data. No studies have been conducted to evidence whether PMHS reduce hospital readmissions. Additionally, all of the evidence in the systematic review was assessed as being of moderate quality, with a high risk of bias (the AXIS tool measured selection bias, measurement bias, and non-response bias). Therefore, the studies that have been conducted could be replicated to a higher standard in order to improve the evidence-base regarding PMHS.

Table 5.5. Evidence supporting the proposed benefits of patient medicines helpline services by Wills et al. (5).

Proposed benefits	Any evidence?	Type of evidence	Quality of evidence
Avoiding harm to patients.	Yes	Quantitative: RRE	Moderate quality, high risk of bias
Improving patient medication adherence.	Yes	Quantitative: SSU	Moderate quality, high risk of bias
Providing assurance to patients that they can access professional help from home.	No		
Improving the patient experience (e.g., patient satisfaction).	Yes	Quantitative: SSU	Moderate quality, high risk of bias
Supporting patient discharge.	No		
Optimising medicines.	Yes	Quantitative: SSU	Moderate quality, high risk of bias
Identifying errors.	Yes	Quantitative: RRE	Moderate quality, high risk of bias
Reducing medicines-related readmissions.	No		
Learning from adverse patient experiences.	No		
Reducing visits to other healthcare services (e.g., GPs, A&E).	Yes	Quantitative: SSU	Moderate quality, high risk of bias
Helping the organisation avoid complaints and possible litigation.	No		
Adhering to the NHS constitution (e.g., patients have a right to receive information).	No		
Improvement in Trust targets and in national surveys.	No		

Abbreviations: A&E = accident and emergency department; GP = general practitioner; RRE = retrospective review of enquiries; SSU = Cross-sectional survey of service users.

5.7 Chapter 5 summary

This chapter reported the findings of a systematic review examining the effectiveness of medicines information services for patients and the general public. Based upon the evidence found, both types of services appear to be valued by service users (satisfaction ratings are excellent, and most respondents would use the services again), and service users report several benefits (e.g., improved knowledge of medicines, improved adherence, feeling reassured, avoiding harm from medicines). However, most of the findings from this systematic review come from studies that collected data using service user surveys, with other data coming from studies examining the types of enquires received to the service. Therefore, most of the data pertaining to the effectiveness of PMHS have used quantitative methods to examine perceived benefits. No studies were found that explored service users' and service providers' views regarding the effectiveness of PMHS using qualitative methods. Therefore, this is a notable gap in the literature.

Whilst conducting this systematic review, it became apparent that there were several additional studies that explored the characteristics of individuals who use PMHS, and the types of enquiries made to PMHS. This information could be useful for exploring the reach of PMHS, since the developers of the RE-AIM framework consider exploring the types of individuals who use an intervention as an aspect of *Reach* (6). The combined findings of these service evaluation studies may be more generalisable than the individual studies alone. Therefore, what is presented next is a systematic review examining the characteristics of individuals who use PMHS, and the types of enquiries they make.

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Chapter 6: A systematic review examining the characteristics of users of NHS patient medicines helpline services, and the types of enquiries they make

6.1 Overview of Chapter 6

As described in the previous chapter for the systematic review examining the effectiveness of PMHS, studies that have examined PMHS have typically been service evaluations of individual sites to describe the characteristics of enquirers and their enquiries, and to report the effectiveness of PMHS using enquirer satisfaction surveys (e.g., (1, 2)). Until now, a review of the literature had not been conducted to bring together the available evidence regarding the characteristics of enquirers to PMHS, nor the enquiries they make. The findings of such a review would be more generalisable to PMHS throughout the UK than individual service evaluations. Study 1 found that NHS Trusts receive on average five calls per week to their PMHS, which suggests that these services could be used more. However, it is difficult to establish exactly how many patients are eligible to use this service, since Hospital Episode Statistics (HES) data do not exist as to the proportion of patients who experience changes to their medicines following hospital discharge (3). A study by Mackridge et al. followed up 99 patients two weeks after being discharged from one of six hospitals in England, and they found that 31 patients (31%) felt they needed support with their medicines (4). Had HES data existed as to the proportion of patients experiencing changes to their medicines following hospital discharge, it may be possible to use the findings by Mackridge et al. to estimate the proportion of patients on average per NHS Trust who require medicines-related support following hospital discharge.

This systematic review could be useful for establishing whether PMHS are under-used by any specific types of patients, and for understanding patients' needs, which could highlight areas for service improvement. The aim of this systematic review was to address the following research questions, in order to develop recommendations for improving PMHS, and potentially, hospital pharmacy services more widely: *What are the characteristics of people who use patient medicines*

helpline services? What are the characteristics of enquiries made to patient medicines helpline services?

This systematic review focussed upon aspects of the 'reach' dimension of the RE-AIM framework. The developers of RE-AIM define *Reach* as the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program, and reasons why or why not (5). In order to examine the representativeness of individuals who use PMHS, where possible, outcomes from the evidence included in this systematic review were compared with Hospital Episode Statistics (HES) admitted patient care and outpatient data for England.

To accord with the mixed methods approach of this doctoral research, any type of study design was included in this systematic review (e.g., qualitative, quantitative, or mixed), as long as the study met our eligibility criteria.

This study was published in the European Journal of Hospital Pharmacy in 2019. However, the journal has requested that the submitted manuscript is presented, rather than the published article. Following the submitted manuscript is a brief summary of the study's findings, and a description of how the study fits within the wider context of the PhD.

6.2 Statement of authorship

This declaration concerns the article entitled:			
A systematic review examining the characteristics of users of NHS patient medicines helpline services, and the types of enquiries they make.			
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** √			
Publication details (reference)	Williams M, Jordan A, Scott J, Jones M. A systematic review examining the characteristics of users of NHS patient medicines helpline services, and the types of enquiries they make. European Journal of Hospital Pharmacy. 2019 Oct 31.		
Copyright status (tick the appropriate statement) I hold the copyright for this material ☐ Copyright is retained by the publisher, but I have been given permission to replicate the material here √			
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… *Formulation of ideas*: I formulated the ideas for this study (90%), with support from my supervisory team (10%). *Design of methodology*: I designed the methodology for this study (90%), with support from my supervisory team (10%). *Experimental work*: I carried out the study (i.e., collected and analysed the data) (100%). *Presentation of data in journal format*: I wrote the study for publication (85%), with support from my supervisory team (15%).		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	05/03/2020

6.3 Submitted manuscript

Table 1 in the submitted manuscript represents Table 7.1 of this thesis.

Table 2 in the submitted manuscript represents Table 7.2 of this thesis.

Table 3 in the submitted manuscript represents Table 7.3 of this thesis.

Table 4 in the submitted manuscript represents Table 7.4 of this thesis.

Table 5 in the submitted manuscript represents Table 7.5 of this thesis.

Figure 1 in the submitted manuscript represents Figure 7.1 of this thesis.

Online supplementary information 1 in the submitted manuscript represents Appendix 6 of this thesis.

Online supplementary information 2 in the published article represents Appendix 7 of this thesis.

Online supplementary information 3 in the published article represents Appendix 8 of this thesis.

A systematic review examining the characteristics of users of NHS patient medicines helpline services, and the types of enquiries they make.

Abstract

Background and objective: Patient medicines helpline services (PMHS) are available from some National Health Service Trusts in the United Kingdom to support patients following discharge. The aim of this systematic review was to examine the available evidence regarding the characteristics of enquirers and enquiries to PMHS, in order to develop recommendations for service improvement.

Methods: Searches were conducted using Medline, EMBASE, CINAHL, Scopus, and Web of Science, on 4th June 2019. Forward and backward citation searches were conducted, and grey literature was searched. Studies were included if they reported any characteristics of enquirers who use PMHS, and/or enquiries received. Study quality was assessed using the AXIS tool. A narrative synthesis was conducted, and where appropriate, weighted means (WM) were calculated. Where possible, outcomes were compared to Hospital Episode Statistics (HES) data for England, to establish whether the profile of helpline users may differ to that of hospital patients.

Results: Nineteen studies were included (~ 4423 enquiries). Risk of bias from assessed studies was 71%. Enquirers were predominantly female (WM = 53%; HES mean = 57%), elderly (WM = 69 years; HES mean = 53 years), and enquired regarding themselves (WM = 72%). Out of inpatient and outpatient enquirers, 50% were inpatients and 50% were outpatients (WM). Six of fourteen studies reported adverse effects as the main enquiry reason. Two of four studies reported antimicrobial drugs as the main enquiry drug class. From two studies, the main clinical origin of enquiries were general surgery and cardiology. Across six studies, 27% (WM) of enquiries concerned medicines-related errors.

Conclusions: Our findings show that PMHS are often used by elderly patients, which is important since this group may be particularly vulnerable to experiencing medicines-related issues following hospital discharge. Over a quarter of enquiries to PMHS may concern medicines-related errors, suggesting that addressing such errors is an important function of this service. However, our study findings may be limited by a high risk of bias within included studies. Further research could provide

a more detailed profile of helpline users (e.g., ethnicity, average number of medicines consumed), and we encourage helpline providers to use their enquiry data to conduct local projects to improve hospital services (e.g., reducing errors).

Registration: PROSPERO CRD42018116276.

Keywords: systematic review, patient medicines helplines, National Health Service, medicines information, drug information, hospital pharmacy.

BACKGROUND

Approximately 40% of patients who have been discharged from hospital may experience medicines-related problems (6, 7). Additionally, patients often lack knowledge about their medications following hospital discharge (8, 9), and many patients report not receiving important medicines-related information (10, 11). Patients may also experience medicines-related errors following hospital discharge, such as dispensing errors and incorrect or missing information on discharge documents (12, 13). Hospital discharge may therefore be a confusing and/or risky period for patients who have recently experienced changes to their medicines.

Consequently, in the UK, hospital-based patient medicines helpline services (PMHS) have become available from some NHS Trusts. The first PMHS was established in the UK in 1992 (14), and a survey study conducted in 2017 found that 52% of NHS Trusts provided a PMHS (15). The function of a PMHS is to enable discharged patients to seek medicines-related support from pharmacy professionals from the healthcare setting where they recently received care. This accords with World Health Organisation (WHO) policy, which states that offering information on medicines via Medicines Information (MI) centres, and providing public education about medicines, are two of twelve essential interventions to promote the rational use of medicines (16).

Studies that have examined PMHS have typically been service evaluations of individual sites to describe the characteristics of enquirers and their enquiries, and to report the effectiveness of PMHS using enquirer satisfaction surveys (e.g., (1, 2)). A recent systematic review examined the evidence regarding the effectiveness of PMHS, concluding that they are typically perceived as positive, advice is usually followed, and users report several positive outcomes (e.g., problems resolved/avoided, and improved health) (17). However, to date, a review of the literature has not been conducted which brings together the available evidence regarding the characteristics of enquirers to PMHS, nor the enquiries they make. The findings of such a review would be more generalisable to PMHS throughout the UK than individual service evaluations. Such information could be useful for establishing whether PMHS are under-used by any types of patients, and for understanding patients' needs, which could highlight areas for service improvement.

Aim

The aim of this systematic review was to address the following research questions, in order to develop recommendations for improving PMHS, and potentially, hospital pharmacy services more widely: *What are the characteristics of people who use PMHS? What are the characteristics of enquiries made to PMHS?*

METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses were used in the planning, conducting, and reporting of this review. The protocol was registered with the International Prospective Register of Systematic Reviews on 21st November 2018 (registration number CRD42018116276) (18).

Eligibility criteria

Studies were included if they reported any characteristics of enquirers who use PMHS, and/or enquiries received. PMHS were defined as: (1) a service for patients and/or carers of patients who received care from the NHS Trust within the UK that provides the PMHS, and not for a specific subset of patients and/or their carers; (2) a service involving distance communication, via any means, between the service user and service provider, instigated by the service user; and (3) a service providing MI, and not general clinical information.

We included published and unpublished studies, abstracts, and conference proceedings that were written in English. We excluded studies if the data were presented in a subsequently published format (e.g., a study in a conference proceeding if it was subsequently published as a full-text article). No restriction was made regarding year of publication.

Studies were only included where the types of enquirers and/or enquiries were based upon either the total number of all enquiries received within a specified period (e.g., six months), or a randomly selected number of enquiries from all enquiries received within a specified period. Studies were excluded if they solely described a subset of all enquirers or enquiries (e.g., only female enquirers, or enquiries about adverse effects), since the focus was upon PMHS, and not upon specific patient groups, issues, or conditions.

Search strategy

Searches were conducted using Medline, EMBASE, CINAHL, Scopus, and Web of Science. Where possible, searches were conducted using both free-text and subject headings. The search strategy was determined for EMBASE, and subsequently adapted to the syntax and subject headings of the other databases (see *Supplementary Information 1* for the EMBASE search strategy). Searches were conducted on 1st August 2017 and updated on 4th June 2019. Forward and backward citation searches were conducted for all included studies. Forward citation searches were conducted on 4th June 2019, using Scopus, Web of Science, and Google Scholar.

The following grey literature sources were searched: grey literature databases, Google and Google Scholar, conferences proceedings, and consultation with experts (see *Supplementary Information 2* for further details).

Screening and selection of studies

Database search results were exported to Covidence (19), duplicates were removed, and studies were screened and selected. Two researchers independently screened all titles and abstracts for relevance, and disagreements were resolved by discussion. Articles meeting the inclusion criteria, or where there was uncertainty, were obtained in complete form. Full text reports were independently examined against the inclusion criteria by two researchers, and disagreements were resolved by discussion.

Data extraction

Data extraction was conducted by one researcher using a data extraction form, with 20% verified by another researcher (see *Supplementary Information 3* for the data extraction form). No discrepancies were found. Details from all data extraction forms were entered in to an excel spreadsheet, in preparation for analysis.

Raw data were not analysed for this systematic review. However, where there was the potential to attain data in a more relevant format, authors of studies

were contacted (e.g., to ask if they would be willing to provide the mean age of enquirers from their retrospective review of enquiries).

Quality assessment of included studies

The AXIS tool (20) was chosen to assess risk of bias and quality within studies. This tool comprises 20 items for assessing cross-sectional studies, and is composed of three subscales. The subscales measure risk of bias (i.e., selection bias, measurement bias, non-response bias, and reporting bias; e.g., 'Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?'), quality of reporting (e.g., 'Were the methods (including statistical methods) sufficiently described to enable them to be repeated?'), and quality of study design (e.g., 'Was the study design appropriate for the stated aim(s)?'). The assessment of risk of bias and quality were used for information, and not to exclude studies. Each included study, for which there was a full report, was independently appraised by two researchers. Only full reports were appraised, since they contained enough information to adequately assess risk of bias and quality of reporting compared to, for example, conference abstracts.
Disagreements were resolved through discussion.

Narrative synthesis

Findings were synthesised in a narrative synthesis around the study objectives, following the guidelines by Popay et al. (21). Where possible, weighted averages were calculated across studies to account for varying sample sizes. Additionally, where possible, outcomes were compared to Hospital Episode Statistics (HES) admitted patient care and outpatient data for England, to examine the representativeness of PMHS enquirers. Since the years of data collection varied across studies, the average of HES data for the past five years were used (2013-14 to 2017-18; (3)).

RESULTS

Study selection

Nineteen studies were identified for inclusion in this review. Figure 1 shows a flow diagram of the study selection process.

Study characteristics

Included studies are presented in Table 1. Eight studies contained data regarding the characteristics of enquirers of PMHS. Eighteen studies contained data regarding the types of enquiries made to PMHS. All studies were retrospective reviews of enquirers and/or enquiries.

Table 1. Studies meeting eligibility criteria for the systematic review examining characteristics of enquirers and enquiries to patient medicines helpline services.

First author, Year published	Study source	Study design	Country of study	Data collection year/s (weeks/months) [a]	Number of enquiries	Outcomes	
						Enquirers	Enquiries
Adam, 2004 (22)	CA	RRE	England	2003 (1 week)	90	X	X
Badiani, 2017 (2)	PS-PR	RRE	England	2015 (9 months)	637		X
Bramley, 2014 (1)	PS-PR	RRE	United Kingdom	2009 (12 months)	312	X	X
Bruce, 1995 (23)	PS-BR	RRE	Scotland	1994-1995 (12 months)	111		X
Burgess, 2009 (24)	CA	RRE	England	2008 (1 month)	17	X	
Cooke, 2010 (25)	CA	RRE	England	2009-2010 (NR)	56		X
Cuthbert, 2013 (26)	CA	RRE	Scotland	NR (6 weeks)	18	X	X
Dhillon, 2001 (27)	PS-PR	RRE	England	NR (3 months)	109	X	X
Dugdale, 2018 (28)	CA	RRE	England	2016-2017 (24 months)	538		X
Hynes, 2013 (29)	CA	RRE	England	2011-2012 (12 months)	209		X
Jones, 2014 (30)	CA	RRE	England	2012-2014 (NR)	234		X
Law, 2015 (31)	CA	RRE	England	2015 (4 months)	109		X
Martin, 2014 (32)	LE	RRE	Wales	2012-2013 (12 months)	262	X	X
Marvin, 2011 (33)	PS-PR	RRE	England	2008 (6 months)	500		X
Price, 2011 (34)	CA	RRE	England	2010-2011 (NR)	51		X
Raynor, 1994 (14)	PS-BR	RRE	England	NR (NR)	NR		X
Sims, 1996 (35)	CA	RRE	England	NR (NR)	> 1000 [b]		X
Teli, 2001 (36)	CA	RRE	England	1999 (NR)	NR	X	X
Williams, 1994 (37)	PS-PR	RRE	England	1993 (NR)	170	X	X

Note. Abbreviations: CA = conference abstract; LE = letter to the editor; NR = not reported; PS-BR = study published as a brief report; PS-PR = published study in a peer reviewed journal; RRE = retrospective review of enquiries.

[a] Of the included studies, the data collection period ranged from one week to twelve months (mean = approximately 31 weeks; seven studies did not report the data collection period length).

[b] This study reported their sample size as 'over 1000'.

Quality assessment and risk of bias within studies

Five studies met our criteria for quality and risk of bias assessment. The overall score and percentage of quality and risk of bias for these studies are presented in Table 2. Fleiss Kappa was conducted, showing that there was substantial agreement between raters (38), K = .72 (95% CI, .56 to .88), p = .000.

Table 2. Quality assessment and risk of bias in full reports of studies meeting eligibility criteria for the systematic review.

First author, Year published	Total [a]	RoB [b]	QoR	QoSD
Badiani, 2017 (2)	50% (10/20)	50% (3/6)	57% (4/7)	43% (3/7)
Bramley, 2014 (1)	63% (12/19)	40% (2/5)	71% (5/7)	57% (4/7)
Dhillon, 2001 (27)	29% (5/17)	100% (3/3)	14% (1/7)	57% (4/7)
Marvin, 2011 (33)	65% (11/17)	67% (2/3)	71% (5/7)	71% (5/7)
Williams, 1994 (37)	35% (6/17)	100% (3/3)	43% (3/7)	43% (3/7)
Average (mean) percentage	48%	71%	51%	54%

Note. Abbreviations: QoR = quality of reporting score (out of a maximum score of 7); QoSD = quality of study design score (out of a maximum score of 7); RoB = risk of bias score (out of a maximum score of 6).

[a] Quality assessment was measured using the AXIS tool, developed by Downes et al. (2016). Depending on the study design, not all RoB items were relevant (i.e., three RoB items pertain to non-response bias, and three of the studies did not recruit study participants since their aim was to only assess PMHS enquiries. Additionally, the study by Bramley (2014) recruited study participants with no non-responders, thus rendering one item obsolete). This accounts for the different maximum Total scores and RoB scores across studies.

[b] The *Risk of Bias* items were reversed, so that the reported percentages reflect the amount of potential bias in each study. However, the AXIS total score was calculated without reversing the *Risk of Bias* items, to ensure that the reported total score percentages reflect the amount of positively coded items in the tool. This accounts for the discrepancy between the total score and the sum of the subscales for each study.

Characteristics of enquirers

Table 3 presents eight studies that reported data regarding the characteristics of enquirers. Enquirers are predominantly female, elderly, and enquiring for themselves.

Table 3. Characteristics of enquirers who use patient medicines helpline services

First author, Year published	*N*	Mean age	% female	% enquired for self	% repeat callers	% discharged inpatients	% outpatients
Adam, 2004 (22)	90	—	62%	—	—	—	—
Bramley, 2014 (1)	312	—	50%	70%	—	—	—
Burgess, 2009 (24)	17	—	—	76%	—	40% [c]	60% [c]
Cuthbert, 2013 (26)	18	70 (SD = 15)	61%	56%	—	—	—
Dhillon, 2011 (27)	109	—	63%	64%	15%	—	—
Martin, 2014 (32)	262	69 (SD = NK)	50%	79%	—	51% [d]	49% [d]
Teli, 2001 (36)	NR	—	—	—	—	72%	18%
Williams, 1994 (37)	170	—	—	—	4%	—	—
Average (mean)		70	57%	69%	10%	54%	42%
Weighted average (mean)		69	53%	72%	8%	50% [e]	50% [e]
HES data, where available		53 [a]	57% [b]	—	—	18%	82%

Note. Abbreviations: HES = Hospital episode Statistics; NK = not known; NR = not reported. Part of the data for the studies by Cuthbert et al. and Martin et al. was obtained from the authors via personal communication.

[a] Range of mean ages over five years of HES data = 52 years to 54 years. Only HES admitted patient care data were used, since mean age was not reported in HES outpatient datasets.

[b] Range of percentages over five years of HES data = 57% to 58%

[c] In the study by Burgess, 2009, two service users were members of the public. Therefore, in order to only use the data regarding inpatients and outpatients, we calculated the percentages of discharged inpatients and outpatients using only the total number of callers who were discharged inpatients or outpatients (*n* = 15).

[d] In the study by Martin, 2014, 21% of service users were reported as being from ophthalmological surgery or clinics, and 22% were not reported. Therefore, in order to only use the data regarding inpatients and outpatients, we calculated the percentages of discharged inpatients and outpatients using only the total number of callers who were discharged inpatients or outpatients (*n* = 149).

[e] The weighted averages for percentages of discharged inpatients and percentages of discharged outpatients are based upon two of three studies, since the sample size was not reported in the study by Teli, 2001.

Types of enquiries

Contact reason

Table 4 presents the findings from fifteen studies that reported reasons for contacting a PMHS. Adverse effects was the category reported as the primary reason for enquiries from six of the fifteen studies, with a weighted mean of 37% of all enquiries.

Table 4. Reason for enquiries reported in studies examining patient medicines helpline services.

Enquiry category	Numbers and percentages of studies reporting the specified category as the primary reason for enquiries		
	Total (*N* = 15)	Range of reported percentages of enquiries (mean; WM)	Sample size range (Total *n*)
Adverse effects	6 (14, 22, 25, 29, 36, 37)	21% - 46% (33%; 37%)	56 - 209 (at least 525[a])
Administration or dosage	5 (23, 28, 31, 32, 34)	21% - 52% (37%; 34%)	49 - 538 (1058)
Interactions	1 (33)	22%	500
Appropriateness or safety of medicines	1 (2)	50%	637
Indications, efficacy or mechanisms of action	1 (35)	34%	At least 1000 [b]
Insufficient information on hospital discharge letter	1 (1)	24%	413

Note. Abbreviations: WM = weighted mean (weighted by sample size). Enquiry categories are listed according to the number of studies within each category. There may be overlap between some enquiry categories, since study authors did not use exactly the same categories.

[a] Two of the six studies did not report their sample size.

[b] This study reported their sample size as 'over 1000'.

Clinical origin of enquiry

Two studies reported the clinical origin of enquiries to their PMHS. For Price et al., (34) the top three clinical origin of enquiries were Surgery (59%), General Medicine (13%), and Paediatrics (6%). For Bramley et al., (1) the top three clinical origin of enquiries were Cardiology (20%), General Medicine (8%), and Ear, Nose and Throat (6%).

Drug classes

Four studies reported the percentage of enquiries by drug class. The largest drug class was reported to be antimicrobial drugs by two studies (19% and 21% of all enquiries) (27, 33) and cardiovascular drugs in a third study (27% of all enquiries) (37). The fourth study, which took place at a mental health Trust, reported atypical antipsychotics as the main drug class (38% of all enquiries) (29).

Enquiries regarding medicines-related errors

Table 5 presents six studies that reported the percentage of enquiries that were regarding medication errors (1, 2, 26, 30, 31, 33). Combined, the studies suggest that between 8% and 39% of enquiries concern errors (mean = 31%; weighted mean = 27%).

Table 5. Studies examining the number of enquiries received by patient medicines helpline services that were regarding medicines-related errors.

Author, Year published	*N*	Total percentage of enquiries regarding errors	Primary error type
Bramley, 2014 (1)	312	8%	Missing medicines (38%)
Badiani, 2017 (2)	637	39%	Transfer of care errors (69%)
Cuthbert, 2013 (26)	18	33%	NR
Jones, 2014 (30)	NR	19%	NR
Law, 2015 (31)	109	20%	NR
Marvin, 2011 (33)	500	34%	Wrong/insufficient information supplied with medicine (49%)

Note. NR = not reported. There may be overlap between some error type categories, since study authors did not use exactly the same categories.

DISCUSSION

This systematic review synthesised the current evidence regarding the characteristics of enquirers to PMHS, and the types of enquiries they make. Included studies were all service evaluations where authors evaluated their own service, and we found the average risk of bias in study articles to be 71%, which we perceive to be high.

Characteristics of enquirers

Our findings suggest that users of PMHS are broadly representative of hospital patients regarding gender, but not age. The average age of helpline enquirers was 69 years, compared to an average age of 53 years for hospital patients. This could reflect that older people tend to seek health information from healthcare professionals directly, compared to younger people who may be more inclined to seek information online (39, 40).

The age difference may also suggest that PMHS are particularly valued as a source of support by people who are at heightened risk with their medicines, since

there is an association between age and polypharmacy (41). Research suggests that polypharmacy increases the risk of prescribing errors (42), adverse drug reactions (43), drug-drug interactions (41), suboptimal adherence (44), emergency department visits (45), unplanned hospital admissions (46), and readmissions (47). Polypharmacy also increases the likelihood that patients will lack knowledge or understanding of their medicines (48). Although no data were found as to the average number of prescribed medicines consumed at the time of contacting a PMHS, approximately 22% of enquiries to PMHS in the UK are regarding interactions, suggesting that a number of enquirers are consuming more than one medicine.

Population projections produced by the Office for National Statistics suggests that there will be a significant increase in the population of older people in the next two decades (49). This may indicate an increased need for MI services in the future, in order to provide support to this growing population.

Our findings, in the context of previous evidence, suggest that there are a number of individuals who may be denied access to some PMHS. We found that 28% of users contacted the service on behalf of a patient, and that 50% of enquiries to PMHS may be from outpatients compared to discharged inpatients. A recently conducted survey of PMHS in England reported that 7% of PMHS (eight NHS Trusts) do not provide advice to carers, and that 5% of PMHS do not provide the service to outpatients (15). This suggests that a proportion of individuals in need of medicines-related support are not able to access it from these particular PMHS. This is important, since one study found that approximately 48% of 500 answered enquiries to a PMHS were considered to have the potential to prevent harm from medicines (33). This highlights the need to advertise this service, and make it available, to *all* patients who may benefit from using it.

Our systematic review found no studies that reported the ethnicity nor educational level/socioeconomic status of enquirers, nor the average number of medicines consumed. Additionally, of the eight studies that reported data regarding the characteristics of enquirers, none of the data were collected within the past five years, suggesting that the relevance and generalisability of the data are now questionable.

Types of enquiries

Our findings suggest that there is wide variation in the percentages of types of enquiries received to different PMHS, since six different categories were reported as being the primary reason for enquiries. This highlights the importance of conducting locally tailored improvement projects whereby PMHS data for an NHS Trust are used to produce recommendations to improve their own services. However, this variation may also be a consequence of sites coding their enquiries using unstandardised enquiry category options, and/or possible confusion regarding how to code certain enquiries (e.g., those that may fit more than one category).

In six of fifteen studies that reported reasons for contacting a PMHS, the largest category of enquiries to PMHS concerned adverse effects. These findings are congruent with the results from the UK National Health Service (NHS) annual Adult Inpatient Survey found that, between 2013-2017, 42-44% of patients (*n* range = 38384-52554) did not recall receiving any information from staff about side effects (11). Consequently, by improving medicines-related counselling to patients at hospital discharge, particularly around side effects, patients may be less likely to need support following discharge (50). However, there is always likely to be a need for PMHS to support patients and carers following patients' discharge from hospital. Evidence suggests that some patients, particularly the elderly, may forget or misunderstand aspects of discharge counselling pertaining to their medicines (8, 51, 52). Additionally, it could be that even if patients are provided with information about potential side effects at the time of discharge, they may still require support later on, at the time when side effects develop.

One proposed benefit of PMHS is that they act as a safety net to identify errors (15). Our synthesis suggests that up to 39% of enquiries to PMHS are regarding medicines-related errors, with a weighted mean of 27%. Medication errors can have significant health and economic consequences, such as adverse drug reactions, reduced medication efficacy, increased use of healthcare services, and death (53). Learning from medicines-related errors in order to implement methods for their reduction is a current NHS and worldwide healthcare priority (53). Royal Pharmaceutical Society-endorsed national standards for operating a PMHS are available (54), one of which is having a mechanism in place to feed back to the Trust medication problems and 'systems errors' identified by patients/carers in order to prevent recurrence. Therefore, a PMHS may provide one avenue for reducing

medicines-related errors, if the information from such enquiries is developed into recommendations and implemented in order to improve practice. However, it is currently unknown what percentage of Trusts currently adhere to this standard, and whether there are specific barriers preventing this from happening.

Recommendations

Further research is needed to establish patients' MI needs and preferences, including those of younger patients. Our findings indicate that enquiries to PMHS are often from elderly patients, and cross-sectional studies suggest that younger people are more likely to seek health-related information online compared to older people (40). However, depending on the source, online information about medicines may not be as reliable as seeking the advice of a pharmacy professional with expertise in MI. Therefore, one way to improve the reach of PMHS may be to establish electronic means to access them, which may be more appealing to younger patients. However, it would be advantageous to first establish the medicines-related needs of younger patients, and how best to engage with them to increase their awareness and use of PMHS.

We recommend that PMHS sites conduct service evaluations in order to provide a more detailed and standardised profile of enquirers (e.g., including ethnicity, educational level/socioeconomic status, and the average number of medicines consumed by patient enquirers). This would help to establish how enquirers compare to the local patient population, and to enable comparisons across sites. Such data could be useful to explore whether certain types of patients are less likely to use the service. This could result in projects to understand why, and whether more can be done to provide a service that is equitable and available for *all* hospital patients who require support with their medicines.
We encourage providers of PMHS to evaluate the types of enquiries they receive (including whether they pertain to a medicine error) by using nationally standardised categories and coding instructions/training materials that are endorsed by the UK Medicines Information network (UKMi). This will enable the types of enquiries received to be more appropriately compared across sites and regions within the UK.

We also encourage sites to use data on types of enquiries to PMHS to produce recommendations for improving local hospital services. For example, six studies reported that enquiries were predominantly about adverse effects, and two

studies reported that enquiries were predominantly about antimicrobial drugs. Therefore, potential projects could involve improving patient leaflets and counselling regarding adverse effects and antimicrobial drugs. Another example could be for sites to monitor the number of enquiries regarding medication errors to establish whether using helpline data to improve practice within the hospital results in a reduced number of calls about errors over time. It would also be useful if sites were more easily able to share learning from their local projects, for example, having the capability to share brief reports via the UKMi network.

Strengths and limitations

This is the first systematic review that has examined the types of enquirers and enquiries of PMHS. This has resulted in our development of recommendations to improve current practice in the operation and evaluation of PMHS, and potentially hospital pharmacy services more widely.

However, the findings of this review may be limited by the small number of studies available to establish averages for certain enquirer characteristics. For example, our findings regarding the average age of participants, the average percentage of repeat enquirers, and the weighted average percentage of inpatients versus outpatients, are all based upon two studies each. Therefore, these findings should be treated with caution, and also emphasise the need for additional, larger studies to examine the profile of enquirers to PMHS.

Relatedly, the findings of this review may also be limited due to the potential lack of high-quality studies currently available. Only five of the nineteen studies in this review met our eligibility criteria for the assessment of quality and risk of bias, since most studies were from conference abstracts and their content was considered too limited to perform a thorough quality assessment upon. We considered the quality of these five studies to be moderate (on average, 48%; range = 29%-65%) and their risk of bias to be high (on average, 71%; range =40%-100%). Therefore, a limitation of this review is that our quality assessment and risk of bias average scores are only based upon 26% of the studies included in this review. However, since the remaining 74% of studies comprised conference abstracts, brief reports, and a letter to an editor, their lack of peer review may arguably raise concern over their quality, also.

Another limitation of this review concerns our comparison of PMHS findings to HES data, since the HES data used in this study is not specifically regarding patients that consume medicines. Also, the HES average age percentage (53%) was calculated from HES admitted patient care data only, since mean age was not reported in HES outpatient datasets. Therefore, the HES age percentage used in this study may not be fully representative of the types of patients who may use a PMHS. Additionally, we compared the findings of this review with HES data over the past five years. Therefore, the data collection years for the studies included in this review and for the HES data did not correspond, which will likely affect the comparison. However, the HES data used were relatively stable over the five years.

Finally, we did not contact all sites that provide a PMHS in the UK to establish whether any local unpublished work could be included in this review. Instead, we contacted authors of included studies within the past ten years to establish the availability of unpublished work from their sites. Therefore, it is possible that other studies may have been conducted with findings that are relevant to this review, but which were not included.

Conclusions

This systematic review synthesised evidence regarding the users of PMHS and the enquiries they make. The service seems particularly appealing for patients who are vulnerable to experiencing medicines-related issues following hospital discharge, since PMHS are often used by the elderly, and elderly patients are more likely to experience polypharmacy. Additionally, over a quarter of enquiries to PMHS may concern medicines-related errors, suggesting that addressing such errors is an important function of this service. However, our study findings may be limited by a high risk of bias within included studies. Further research could provide a more detailed profile of helpline users (e.g., ethnicity, average number of medicines consumed). We recommend standardising the way that PMHS data are categorised and reported so that data are more easily comparable and collated across sites for a more generalisable picture of PMHS use. We encourage PMHS providers to use routinely collected data to conduct local quality improvement projects (e.g., to reduce medicines-related errors, and improve patient MI leaflets/counselling), and to share project findings with other PMHS providers.

LIST OF ABBREVIATIONS

MI = medicines information; NHS = National Health Service; PMHS = patient medicines helpline service; UK = United Kingdom; UKMi = United Kingdom Medicines Information Network.

DECLARATIONS

Ethics approval and consent to participate

Not applicable, since the research used secondary data sources collected from published and unpublished studies.

Consent for publication

Not applicable.

Availability of data and material

Not applicable, since no primary data were collected or used for this research.

Competing interests

The authors declare that they have no competing interests.

Funding

The lead author was funded by a Graduate School Scholarship provided by the University of Bath. The funder had no role in the study design, the collection, analysis and interpretation of the data, the writing of the report, and the decision to submit the article for publication.

Authors' contributions

The study was designed by MW and MJ, with advice from AJ and JS. MW was involved in all stages of the systematic review process, and drafted the manuscript.

MJ, AJ and JS were involved in the screening of titles and abstracts. MJ was involved in discussions regarding the inclusion of studies and the quality assessment of studies. All authors read, provided feedback and approved the final manuscript.

Acknowledgements

We would like to thank Danielle Cox and Tess Rugg for their help with the screening and quality assessment stages of this review.

6.4 Data access statement

As specified in the published article, no data are available, since no primary data were collected for this research.

6.5 Chapter 6 summary

This chapter presents the findings of a systematic review that examined the available evidence regarding the characteristics of users of PMHS, and the types of enquiries they make. Therefore, this study fits within the wider context of the PhD by exploring the *Reach* aspect of the RE-AIM framework for establishing the impact of interventions.

The findings show that PMHS are particularly used by elderly patients, which is important considering that this group may be particularly vulnerable to experiencing medicines-related issues following hospital discharge. However, as with the systematic review examining the effectiveness of PMHS, the quality of evidence was found to be moderate, and there was a high risk of bias (the AXIS tool measures selection bias, measurement bias, and reporting bias).

This systematic review is limited by being reliant upon retrospective reviews of enquiries, using already collected and coded data. There were noticeable gaps pertaining to the demographics of enquirers (e.g., no studies had examined the ethnicity of enquirers, nor established their socioeconomic status). A study by Peconi et al. (55) examined 400,000 enquiries to the telephone advice service NHS Direct wales. They found that deprivation had no consistent effect on demand for the service. However, callers were typically contacting the service about themselves (58%), more females called the service than males (62% were female), and most callers were of white ethnicity (98%). Aside from ethnicity, for which no data were available, these findings accord with the findings from the systematic review presented in this chapter. Similarly, a study by Cook et al. examined 1,342,245 calls to NHS Direct in England (56). Findings showed that all mixed ethnic groups had a higher than expected uptake of NHS Direct, whereas Black and Asian ethnic groups had lower than expected uptake. The authors conclude that barriers to uptake in certain ethnic groups needs to be examined, in order to recommend ways to ensure that the service is used by everybody who may need support. This study highlights

the importance of examining the ethnicity of enquirers to telephone helpline services, such as PMHS.

The findings also show that, across six studies, most enquiries to PMHS are regarding side effects. However, further research is needed to establish exactly what advice is provided by PMHS staff to enquirers, and whether the advice is actually able to help the enquirer. It could be that, if patients and carers contact the service because the patient is currently experiencing a side effect, then the pharmacist dealing with the enquiry may not be able to help other than recommend that the patient seek urgent medical help, depending on the severity of the situation. This could mean that some enquiries to PMHS may be inappropriate and better dealt with elsewhere. This is currently conjecture, since data are not available to ascertain this. Relatedly, the findings of this review show that a sizeable number of enquiries concern medicines-related errors (between 8% and 39%, across six studies). This suggest that, had the errors not occurred in the first place, the enquiries would not be necessary. Therefore, using enquiry data to try to improve hospital services (i.e., reducing errors) will likely reduce the number of enquiries received to PMHS over time. Further research is needed to establish whether this is the case, and if so, the extent to which enquiries can be reduced over time. As established in Study 1 of this thesis, NHS Trusts that provide a PMHS receive five enquiries per week on average (15). If the number of enquiries is able to be reduced over time through using the content of enquiries to devise healthcare quality improvement projects, providers of PMHS may then have the resources to promote their service more thoroughly in order to reach as many patients and carers who may need medicines information. As also established in Study 1, the promotion of PMHS was found to be poor across NHS Trusts within England (15).

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Chapter 7: Pharmacy professionals' experiences and perceptions of providing NHS patient medicines helpline services: A qualitative study.

7.1 Overview of Chapter 7

Study one comprised an online survey examining PMHS using the RE-AIM evaluation framework (i.e., how many NHS Trusts in England provide a PMHS, how PMHS are operated, and what pharmacists think are their benefits). However, a limitation of survey studies is that surveys include questions and answer options that are important to the researcher, rather than allowing participants to provide information that is important to them. Therefore, a limitation of Study 1 is that it did not seek to provide pharmacy professionals with the opportunity to describe in detail their perceptions of PMHS. For example, it did not explore pharmacy professionals' perceptions as to the benefits and possible limitations of PMHS, nor perceived ways that PMHS could be improved. Establishing this may help to increase the availability and reach of PMHS. To achieve this, qualitative methods would be more appropriate. Therefore, this study forms part of a sequential mixed methods approach along with Study 1, whereby the findings from Study 1 were explored ideographically using qualitative research methods. This is an example of what Creswell and Plano Clark call an *emergent* mixed methods design, whereby a complimentary research study was subsequently designed and conducted in order to elucidate previous findings (1).

In line with healthcare quality improvement approaches, services are likely to be improved by seeking to understand the perceptions of service providers (2). As established in the systematic reviews presented in previous chapters, no qualitative studies had been conducted to examine pharmacy professionals' perceptions of operating a PMHS. Therefore, the aim of this novel qualitative study was to address this gap in the literature by exploring pharmacy professionals' experiences and perceptions of providing a PMHS, their benefits, and areas for improvement. In particular, this study addressed the following research question: *What are pharmacy professionals' experiences and perceptions of providing an NHS PMHS?*

This study was published in BMC Health services Research in 2020. Therefore, the published article is presented. Following the article is a brief summary of the study's findings, and a description of how the study fits within the wider context of the PhD.

7.2 Statement of authorship

This declaration concerns the article entitled:			
Pharmacy professionals' experiences and perceptions of providing NHS patient medicines helpline services: A qualitative study.			
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** √			
Publication details (reference)	Williams M, Jordan A, Scott J, Jones M. Pharmacy professionals' experiences and perceptions of providing NHS patient medicines helpline services: A qualitative study.		
Copyright status (tick the appropriate statement) I hold the copyright for this material √ Copyright is retained by the publisher, but I have been given permission to replicate the material here ☐			
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… *Formulation of ideas*: I formulated the ideas for this study (90%), with support from my supervisory team (10%). *Design of methodology*: I designed the methodology for this study (90%), with support from my supervisory team (10%). *Experimental work*: I carried out the study (i.e., collected and analysed the data) (100%). *Presentation of data in journal format*: I wrote the study for publication (85%), with support from my supervisory team (15%).		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	02/05/2020

7.3 Published article

The published article represents pages 134 to 144 of this thesis (11 pages).

Table 1 in the published article represents Table 7.1 of this thesis.
Table 2 in the published article represents Table 7.2 of this thesis.

Additional file 1 in the published article represents Appendix 9 of this thesis.
Additional file 2 in the published article represents Appendix 10 of this thesis.

BMC Health Services Research

RESEARCH ARTICLE Open Access

Pharmacy professionals' experiences and perceptions of providing NHS patient medicines helpline services: a qualitative study

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Abstract

Background: Patient medicines helpline services (PMHS) have been established at some National Health Service (NHS) Trusts in England, with the aim of providing medicines-related support to patients after they have been discharged. Addressing an important knowledge gap, this qualitative study sought to examine pharmacy professionals' experiences and perceptions of their PMHS, including perceived benefits of the services, and areas for improvement.

Methods: Invitations to participate were sent to all NHS Trusts within England that were known to provide a PMHS ($n = 117$). Semi-structured interviews were conducted via telephone with 34 pharmacy professionals who provide a PMHS (female = 76%, male = 24%; predominantly from Acute NHS Trusts, 76%). Interviews were audio-recorded and transcribed verbatim. The RE-AIM framework for evaluating interventions (RE-AIM: Reach, Effectiveness, Adoption, Implementation, Maintenance) informed the development of the interview schedule and the analysis of the data using framework analysis.

Results: Two themes were generated from the analysis: *Resources,* and *Perceived benefits*. Findings illustrate how providing a PMHS with limited resources (e.g., no specific funding, understaffed) negatively impacts the implementation, maintenance and reach of PMHS, and the ability to evidence their effectiveness. Despite operating with limited resources, PMHS are considered to have many benefits for patients and healthcare organisations (e.g., providing a 'safety net' to patients during the transfer of care period, providing reassurance to patients, helping to optimise patients' medicines, resolving medicines-related errors, reducing the burden upon other services, and providing the potential to improve hospital services based upon the content of enquiries). However, actually establishing the effectiveness and cost-effectiveness of PMHS is challenging due to perceived logistical difficulties of collecting data, and the difficulty measuring hard outcomes (e.g., prevention of readmissions).

(Continued on next page)

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(Continued from previous page)
Conclusions: PMHS are typically perceived to be under-resourced, although they are considered by pharmacy professionals to have several benefits for service users and NHS Trusts. For those sites that provide a PMHS, we recommend using enquiry data to improve hospital services, and to share ideas for implementing and maintaining a PMHS within a resource-limited context. High-quality research is needed to evidence the effectiveness and cost-effectiveness of PMHS, which may help to secure adequate resources for this service in the future.

Keywords: Patient medicines helplines, National Health Service, Medicines information, Drug information, Hospital pharmacy, Hospital discharge, Medication errors, Qualitative, Framework analysis, RE-AIM

Background

Patients often experience changes to their medicines regimen while they are in hospital, and healthcare policy in the United Kingdom (UK) requires that patients' medicines are managed optimally after discharge from secondary care [1, 2]. However, a growing body of evidence highlights that a number of patients in the UK lack knowledge of their medications following hospital discharge [3], and report not receiving important information about their medications [4–7]. Additionally, findings suggest that up to 40% of patients who have been discharged from hospital may subsequently experience medicines-related problems or need support with their medicines [8–11].

Patient medicines helpline services (PMHS) have been set up by some National Health Service (NHS) Trusts[1] in England, with the aim of providing support to recently discharged patients regarding changes to their medicines regimen as a result of their hospital care. The first PMHS was set up in 1992, and a survey study conducted in 2017 reported that 52% of NHS Trusts in England provided a PMHS [12]. A recent systematic review examined the evidence regarding the effectiveness of PMHS, concluding that PMHS are typically valued by service users (e.g., satisfaction ratings are excellent) and that the advice provided to service users is usually followed. Results of the review also identified that service users report several positive outcomes of consulting a PMHS which include resolution or avoidance of medicines-related problems, feeling reassured, and improved health [13]. This systematic review highlights that, to date, studies examining PMHS have mainly examined the views of service users, using quantitative methods.

PMHS are likely to be improved by seeking to understand the perceptions of not only service users but also service providers [14]. To date, the only studies to examine pharmacy professionals' views of PMHS are survey studies examining how PMHS are provided [12, 15, 16]. For example, the most recent was an online survey conducted in 2017 that examined how PMHS are provided by NHS Trusts in England ($N = 117$) [12]. Findings showed that PMHS are under-used, under-promoted, and not sufficiently available to patients. Since the aim of the survey study was to provide a general overview as to how PMHS are provided, the authors did not seek to explore pharmacy professionals' perceptions regarding the underuse of PMHS, nor why the implementation of PMHS are limited in several respects. This study also did not directly seek pharmacy professionals' views regarding the effectiveness of PMHS. Instead, participants selected options from a list of perceived benefits that were compiled by three medicines information (MI) pharmacists [17], which may have biased the results.

Qualitative research can be important for understanding perceived reasons why healthcare services are effective or not, and how services can be improved [18, 19]. The idiographic approach to studying phenomena is unique to qualitative methods and enables greater importance to be placed on studying individuals' insights, understandings, and meanings of their lived experiences [20]. With the need to adopt a more in-depth and idiographic approach to exploring pharmacy professionals' experiences and perceptions of providing a PMHS, qualitative methods are well suited to address this important issue.

Aims

The aim of this novel study was to use qualitative methods to explore pharmacy professionals' experiences and perceptions of providing a PMHS, in order to develop recommendations for service improvement for the benefit of users and providers of PMHS. In particular, this study addressed the following research question: *What are pharmacy professionals' experiences and perceptions of providing an NHS patient medicines helpline service?*

Method

Study design

A qualitative interview design was chosen to explore pharmacy professionals' experiences and perceptions of providing a PMHS. The authors adopted the epistemological position of pragmatism [21].

Participants and recruitment

Participants were eligible for this study if they were either a Chief Pharmacist at an NHS Trust within England

that operates a PMHS, or a pharmacy professional who operates a PMHS at their NHS Trust within England. Chief Pharmacists were invited to participate to provide a perspective as to how PMHS are beneficial within the wider organisation. Pharmacy professionals who operate a PMHS were invited to participate, since they see first-hand the benefits and potential limitations of this service. Eligible participants were required to be registered with the General Pharmaceutical Council (GPhC), which is the UK licensing body for pharmacy professionals.

Our estimated sample size was based upon that of published qualitative studies of healthcare professionals' (HCPs) perceptions of healthcare services, and recommendations in literature [20]. We therefore aimed to conduct between 20 and 30 interviews. Upon reaching the thirtieth interview, we decided to invite the few remaining NHS Trusts that provide a PMHS in England who had not yet been contacted, to ensure that all relevant sites had the opportunity to participate ($n = 117$ Trusts, [12]). This resulted in a total of 34 participants.

Table 1 provides an overview of participant characteristics (see Additional file 1 for anonymised information regarding each participant). Most participants were female, and employed within an acute Trust.

Data collection

Interviews were chosen as the data collection method in order to enable flexibility through the use of probes and unplanned questions. Telephone interviews were chosen to enable pharmacy professionals throughout England to be easily interviewed. Each participant was interviewed once.

An interview schedule was developed for the purpose of exploring participants experiences and perceptions of their PMHS, and was informed by the RE-AIM framework [22]. RE-AIM comprises five dimensions that are considered important for evaluating the impact of healthcare interventions: *Reach* (whether an intervention is reaching everyone who would benefit from it; perceived reasons for underuse); *Effectiveness* (the positive and negative consequences of an intervention); *Adoption* (whether an intervention is adopted by settings that could provide it; perceived reasons for or against adoption); *Implementation* (extent to which an intervention is delivered as intended); and *Maintenance* (extent to which an intervention becomes a stable, enduring part of the behavioural repertoire of an individual/organisation). We ensured that questions pertaining to each of the five RE-AIM dimensions were included in the schedule. For example, for *Adoption*, participants were asked

Table 1 Participant characteristics

Characteristic		Participants ($n = 34$)
		n (%), or mean years (SD; range)
Gender	Male	8 (24%)
	Female	26 (76%)
Age		39 (9.50; 25 to 59)
Ethnicity	White or White British	27 (79%)
	Asian or Asian British	7 (21%)
Job title	Senior or Lead MI Pharmacist	16 (47%)
	Chief Pharmacist	4 (12%)
	MI Pharmacist	4 (12%)
	MI Manager	3 (9%)
	Pharmacist	3 (9%)
	Senior or Lead Pharmacist	2 (6%)
	Junior Pharmacist	1 (3%)
	Senior or Lead MI Technician	1 (3%)
Number of years employed as a pharmacy professional		16 (9.97; 3 to 35)
Number of years working on a PMHS		6 (3.71; 0.5 to 12)
NHS Trust type	Acute	26 (76%)
	Mental health	3 (9%)
	Integrated (two or more types)	2 (6%)
	Specialist	2 (6%)
	Community	1 (3%)

Note. Abbreviations: MI = medicines information; PMHS = patient medicines helpline service. NHS = National Health Service

the following: "Please could you describe why your patient medicines helpline service was developed?" (see Additional file 2 for the interview schedule). The topics of the interview schedule are presented in Table 2. The interview schedule was developed by the study authors in accordance with established conventions for semi-structured interviewing [23–25]. The interview schedule was not piloted. However, once drafted, the interview schedule was reviewed by three MI Pharmacists with expertise in operating a PMHS, with refinements made based upon their feedback.

During data collection, the interview schedule served as a flexible guide for interviews, enabling participants to discuss aspects of their PMHS that were important to them. All interviews were audio-recorded.

After their interview, the following background data were collected from each participant over the telephone: age, gender, ethnicity, job title, number of years employed as a pharmacy professional, and number of years' experience of operating or providing a PMHS.

All data were collected by a trained interviewer (MW) between May and October 2018. Interview duration ranged from 16 to 53 min (mean = 30 min).

Data analysis

All audio-recorded interviews were transcribed verbatim into separate Microsoft Word documents. Framework analysis (FA) was used to analyse the transcribed data. FA is a systematic, rigorous and transparent technique for organising, describing, and interpreting data, which has been used within health research [26–28]. FA was chosen instead of other thematic methods because the RE-AIM framework was to guide the analytic framework, and also because FA was developed to help manage relatively large qualitative datasets [27].

Table 2 Main topics for interviews with pharmacy professionals regarding their patient medicines helpline service

Topics
1. Perceived purpose of their patient medicines helpline service.
2. Why the patient medicines helpline service was set up.
3. Perceived qualities of a good patient medicines helpline service.
4. How the quality of the patient medicines helpline service is ensured.
5. Perceived benefits of operating a patient medicines helpline service.
6. Perceived challenges of operating a patient medicines helpline service.
7. Perceptions as to whether and in what ways the patient medicines helpline service meets service users' needs.
8. Perceptions as to whether and in what ways the patient medicines helpline service is cost-effective.
9. Perceptions as to whether and in what ways any aspects of the patient medicines helpline service could be improved.
10. Perceptions as to the usage of the patient medicines helpline service.
11. Perceptions as to whether they feel they have all the resources needed to provide their patient medicines helpline service the way they want to.
12. Perceptions as to procedures that are in place when an enquiry reveals that there has been a medicines-related error, and/or there is the potential to learn from an enquiry.

Analysis involved the following stages, as outlined by Ritchie and Spencer [29]: familiarisation with the data, coding, developing an analytical framework, indexing, charting, and interpretation. Being a flexible approach, FA can be used for deductive, inductive, or combined qualitative analysis [27]. A combined approach was used for the present study, whereby the five aspects of the RE-AIM framework were used as categories, and codes were developed from the data if they pertained to one of these five categories. However, inductive coding was also conducted as new concepts became apparent. All interview transcripts were uploaded into NVivo version 12 [30], which was used for the framework development and indexing stages. The only deviation to the FA stages was that Iterative Categorisation (IC) [31] was used in place of charting. The choice to use IC was made in order to increase transparency and rigour. IC leaves a clear audit trail, which provides a route back to the indexed data. With IC, each indexed code within the framework was exported from NVivo to a Microsoft Word document. Each document was then reviewed line-by-line, summarizing and organising the findings iteratively into points that represented commonalities and differences across participants. This ensured transparency as to which participants contributed to each point (see Neale [31] for further details). Final themes were generated after re-reading all of the IC documents. Study participants did not provide feedback on the findings, since evidence suggests that such checks may not improve study findings [32].

Establishing quality in qualitative research

Yardley's criteria for demonstrating the quality of qualitative research were met [33]. For *sensitivity to context*, previous literature was reviewed, and a theoretical framework (RE-AIM) was used to guide data collection and analysis. For *commitment and rigour*, FA and IC stages were followed, and a 'paper trail' approach was used. Credibility checks were conducted, where each stage of the analysis was checked by another member of the research team to verify that the identified codes and themes were appropriate. Additionally, the consolidated criteria for reporting qualitative research (COREQ) were followed [34]. For *coherence and transparency*, the study results are grounded in example quotations from the raw data. A reflective diary was used throughout the process of data collection and analysis, to record thoughts about each interview, contextual features that

may have influenced interviews, and/or any ways that interviews could have been improved in order to enhance subsequent interviews. For *impact and importance*, the study findings were used to develop recommendations for improving the provision of PMHS.

Results

Two themes were generated from the analysis: *Resources,* and *Perceived benefits*. *Resources* identifies that PMHS are often provided with limited resources. *Perceived benefits* identifies that PMHS are perceived to have several benefits, although evidencing the benefits is considered challenging.

Resources

Participants described several resources that are considered useful for ensuring that they provide a high-quality PMHS. These included mechanisms for documenting enquiries, support of colleagues within the wider organisation (e.g., to promote the service), support of local and regional MI centres for conducting quality checks, and the use of standard operating procedures and training materials for new staff. Because PMHS function to resolve enquiries resulting from care received from secondary care services, participants expressed the need for local, Trust-based resources to achieve this (e.g., discharge summaries, blood results, drug charts, inpatient notes, access to HCPs involved in their care). Some participants described how their service is also available for patients of neighbouring Trusts, and that lacking local resources to answer enquiries may result in delayed help for these patients.

"*We offer the service to other places now… We don't have access to their patient records, which is not ideal for operating a patient helpline. But we have a system in place where, if we need to look at the records, we have a contact to ring... And they will have a look at, say, the patient's discharge letter and perhaps fax that over to us or email it to us*." (P1, Lead MI Pharmacist, Acute Trust).

Participants perceived one of the biggest challenges for adopting, implementing and maintaining a PMHS to be inadequate funding and resources. Many participants described the lack of specific funding and resources for their service.

"*We initially formed and set up the service and took it live with no additional cost to the pharmacy department. It was an additional role added in to the portfolio of our medicines information department*." (P4, Chief Pharmacist, Acute Trust).

Some participants described the difficulty in obtaining funding due to the low number of enquiries received to the service. This suggests a difficult situation where the numbers of enquiries are too small to justify additional funding/resources, yet without additional funding/resources, the number of callers is unlikely to increase.

"*I think it would be difficult with the number of enquiries we get to say that there is, you know, a pressure. Or to support a business case for getting additional staff*." (P13, Senior MI Pharmacist, Acute Trust).

Although some participants considered their PMHS to be inexpensive to run, other participants described that funding is needed, and that not having funding has a negative impact upon the service.

"*I think it's probably as good as it could be, given the amount they're investing in it, to be honest. So, what they're prepared to put in, they'll get out.*" (P16, Pharmacist, Mental Health Trust).

A consequence of limited funding/resources is that the availability of PMHS may be inadequate. Some providers acknowledged that they do not currently meet national standards for satisfactory PMHS availability (i.e., available for at least 4 hours a day, 5 days a week), but that some provision is better than none. At some sites, pharmacy professionals described how, even when their helpline should be manned, they may not always be available to answer enquiries due to other commitments and staffing issues.

"*You've got discharges to do, new patients to see, high risk patients, and you've got those that have been discharged that have phoned up with queries. So, it's kind of going into more of a clinical pot to be prioritised and answered at some point during the day*." (P20, Lead Pharmacist, Specialist Trust).

At some sites, the enquiries are received only by voicemail, which means that a caller will never directly speak to a pharmacy professional when they contact the service for help. Providing a service with limited access and availability, such as a voicemail service, was acknowledged as having potential negative consequences. For example, callers may feel frustrated and seek advice elsewhere, or not seek help at all. Limited access and availability may therefore also have an impact upon the use of the service.

"*I think being able to have someone answering the phone more consistently throughout the day [would improve its use]… I think if there's no-one there to answer the phone, then people don't leave a message. So, I think we are probably missing people because of that*." (P13, Senior MI Pharmacist; Acute Trust).

Since the majority of enquiries to PMHS were considered to be relatively straightforward, some participants described that a triaging system would be cheaper and more efficient, whereby a pharmacy technician receives and answers enquiries, and forwards more complex ones to a pharmacist. Some sites had already implemented such a model.

Lack of resources was also discussed in relation to the perceived under-promotion of PMHS. Most participants commented that their service is not promoted enough, and in some cases, not promoted at all. Reasons included not having the time to monitor the advertising, and fear of over-promoting the service and not being able to cope with the demand.

"*It was decided that we would just promote through cards [given out with prescriptions]. We didn't want to sort of over-promote the service and then have me drowning in enquiries. Because I'm on my own*." (P7, MI Pharmacist, Acute Trust).

This suggests that, due to lack of time/resources, some PMHS providers are purposefully restricting the use of their service. However, this may mean that some patients will not learn of the existence of the service, which may result in them being inconvenienced or suffering as a consequence of improper use of their medicines. Participants commented upon the link between the lack of promotion of their service, and its perceived underuse.

"*I think it could be more widely used, if we found ways of promoting it better. So, we need to make sure that the number is on every piece of paper that comes out of any department. And then I think we would have more uptake*." (P15, MI Manager, Acute Trust).

Some participants described the benefit of particular promotional methods. For example, promoting the service via the discharge summary is not only free advertising, but it also ensures that the service is promoted to every discharged patient, which increases the number of enquiries.

Despite often providing a PMHS with limited resources, most participants commented that answering enquiries to their PMHS and helping patients provides them with job satisfaction. This could be a motivation for continuing to run a PMHS, despite limited resources.

"We love providing the service. We really do…When you've resolved something for a patient, even if it's very simple for us, obviously it's concerned them enough to give you a ring. When you've resolved an issue, it actually kind of leaves you with quite a nice fuzzy feeling." (P26, Lead MI Pharmacist, Acute Trust).

Perceived benefits

Participants described several perceived benefits of providing a PMHS. Primarily, PMHS were perceived to be beneficial for providing patients with personalised, expert support during the transfer of care period. PMHS were considered necessary in order to address often inadequate discharge processes in which discharge counselling is limited. Discharges were perceived to be inadequate for several reasons, such as the difficulty of patients/carers retaining a large amount of information provided on discharge, HCPs having insufficient time to explain everything, and discharges occurring out-of-hours when HCPs are often unavailable.

"*It's a safety net. The pharmacists are quite time-pressured on the wards but unfortunately counselling of patients on discharge probably doesn't happen as much as we would like. So, the advice line helps sort of mop up any missed important counselling points really, for those proactive patients that call us*." (P2, Lead MI Pharmacist, Acute Trust).

The above quotation also highlights that PMHS may not reach all patients who require support, since the onus is upon the patient or carer making contact with the service. It is likely that there is an unknown number of patients who require support with their medicines after discharge but who are *not* proactive and do not call the hospital's PMHS.

Perceived benefits upon patients and carers also included improving patients' adherence and knowledge of their medicines, helping patients take medicines safely and therefore potentially avoiding harm, and improving patients' experiences of care. No participants described any perceived adverse effects of providing a PMHS.

"*[A benefit of the helpline is] them continuing to take the right medicines at the right times in the right way, meaning that they have the best outcomes and have the most, you know, optimal use of their medicines*." (P21, Lead MI Pharmacist, Acute Trust).

Offering a helpline also enabled pharmacists to provide reassurance to patients who have queries about their medication. This was considered to be an important function, and may be pivotal in encouraging patients to use medication appropriately.

"*Sometimes, people just want some reassurance. We know that patients don't often take their medications as they're prescribed. And actually, often that can be due to kind of misconceptions that they have about their medicines. Or concerns. Being able to speak to someone in a bit more of a calm environment than a ward post-discharge, can be all patients need sometimes to consider continuing to take their medicines*." (P33, MI Manager, Acute Trust).

Extending the benefits of PMHS beyond the individual level, participants described how PMHS successfully sought to positively promote pharmacy services and the Trust at a wider level (e.g., showing continued responsibility after discharge).

"*I think it [PMHS] sheds a positive light on to the Trust. It shows that the Trust cares about their patients. And you know, their level of responsibility doesn't end when the patients are physically discharged*." (P12, Pharmacist, Mental Health Trust).

Participants also described the PMHS as being a mechanism for catching and/or resolving medicines-

related errors, which can provide a learning and improvement opportunity for the Trust.

"Sometimes queries do bring out that there has been an error. So sometimes patients have got home and they haven't got something that they should've had, or they've got somebody else's something that they shouldn't have. So, it's making sure that those errors are fed back to the appropriate people and filling in the appropriate incident reporting forms, as well." (P21, Lead MI Pharmacist, Acute Trust).

Participants also described how use of PMHS could benefit the trust more widely though acting as a mechanism for fixing medication-related issues before they result in formal complaints to the Trust.

"You would hope you'd have less formal complaints. Because it's the first place that people come to, we can hopefully resolve any queries that they've got before, you know, they escalate in to something else whereby they then need to make a more formal complaint." (P14, Chief Pharmacist, Acute Trust).

Other perceived benefits for the Trust included preventing hospital readmissions, reducing the burden upon other services, and the potential to learn from enquiries in order to improve services (e.g., examining trends in the types of enquiries received to improving discharge counselling and/or patient information leaflets).

"*We can collect [enquiries], and where we get a trend, what we'll do is we'll go to the department and say "We've had a fair number of enquiries about this. You might want to have a rethink about your system.""* (Participant 29, MI Pharmacist, Acute NHS Trust).

Although several perceived benefits were described, many participants reported being unsure regarding the *actual* effectiveness of their PMHS, since the effectiveness of their service had not been evaluated. Measuring the effectiveness of PMHS was considered to be problematic for numerous reasons including difficulties with collecting data from PMHS users (e.g., lack of time and resources, difficulty obtaining consent, and previous response rates being low).

"*We are supposed to send out questionnaires to patients who have used the service to find out about their experiences… It's very very rare that any of them respond*." (P34, Senior MI Pharmacist, Acute Trust).

The following quotation also highlights how, for some Trusts, the underuse of PMHS can hinder evidencing the effectiveness of the service, since it may be difficult to collect meaningful data from a small sample.

"*We've definitely not done any sort of studies looking at [the effectiveness of the service]. And our numbers are probably too small for it to really be significant details*." (P9, Chief Pharmacist, Specialist Trust).

In addition to the challenges around the logistics of collecting data, participants also described the difficulty of measuring effectiveness and cost-effectiveness in order to evidence that providing their PMHS is worthwhile (e.g., the difficulty evidencing what would have happened had the service not existed, the difficulty evidencing that the service reduces readmissions and/or the burden upon other healthcare services, and the difficulty measuring actual outcomes for patients instead of their perceived outcomes).

"*To actually benchmark and measure better outcomes is incredibly difficult. How do you actually show to the Trust that Fred Bloggs… how do you actually demonstrate that his outcomes were better because he had that intervention? … It's very difficult for the Trust to know that that service is good."* (P18, Chief Pharmacist, Integrated Trust).

Despite this, participants commented on the importance of using enquiry data to show the value of their PMHS. For example, performance statistics (e.g., number of enquiries received per month, types of enquiries) can be produced for the Trusts' pharmacy dashboard, senior managers, and the hospital executive team.

Discussion

This study explored the experiences and perceptions of providing a PMHS in a sample comprising 34 pharmacy professionals. Two themes were generated: *Resources*, and *Perceived benefits*. The findings illustrate how providing a PMHS with limited resources (e.g., specific funding, adequate staffing) impacts upon their implementation, maintenance, reach, and the ability to evidence their effectiveness. Despite this, PMHS are considered to have a number of benefits for patients and healthcare organisations (e.g., providing a 'safety net' to patients during the transfer of care period, providing reassurance, helping to optimise patients' medicines, preventing readmissions, and reducing the burden upon other healthcare services). However, actually establishing the effectiveness and cost-effectiveness of PMHS is challenging due to perceived logistical difficulties of collecting data, and the difficulty measuring hard outcomes.

Our finding that PMHS are often provided with limited resources corresponds with a recent survey study showing that the main reason why 48% of NHS Trusts in England in 2017 did not provide a PMHS was also due to lack of staffing/resources [12]. Our findings also suggest that a particular challenge for proving a PMHS was having pharmacy professionals being available to answer calls during the working day. This accords with findings of the same survey study, showing that, although 86% of Trusts that provide a PMHS reported it as being accessible for at least 4 hours per day, only 57% of Trusts reported that their PMHS was accessible for eight or more hours per day. Additionally, 29% of Trusts

reported that contact with a pharmacy professional is not always available during advertised hours.

The lack of access and availability of PMHS may mean that patients choose to seek advice elsewhere, increasing the burden upon primary care. A recently conducted systematic review found that, if a PMHS was not available, patients and carers would most likely seek the advice of their GP instead [13]. This is topical, given that the average waiting time from booking a standard appointment to seeing a GP in England in 2016 and 2017 was approximately 2 weeks [35]. A delay to receive appropriate medicines-related support may have implications for patients regarding the optimisation of their medicines and their ability to be adherent, which may impact their wellbeing. Patients and carers also have other options, such as visiting a community pharmacist or contacting NHS 111 (a general health information service in England). However, Badiani et al. found that, out of 200 enquiries received to their PMHS, 74.5% required access to hospital-based resources (e.g., patient records, and healthcare providers) [36]. Thus, community pharmacists and NHS 111 are currently unlikely to be able to answer the majority of enquiries.

Our findings suggest that, from the perspectives of pharmacy professionals, PMHS have a number of benefits for patients and the healthcare organisation. These perceived benefits are consistent with the outcomes reported in a recently conducted systematic review examining the effectiveness of PMHS (e.g., patients feeling reassured, patients' improved use of medicines) [13]. However, the outcomes in this systematic review are also based upon perceptions, since the identified studies primarily involved surveying service users, or having clinicians rate enquiries and answers in order to hypothesise the impact upon patients. Therefore, to date, no studies have examined hard outcomes from using a PMHS (e.g., readmissions). This accords with our finding that pharmacy professionals view measuring hard outcomes from PMHS as challenging.

Participants' description of their PMHS as a 'safety net' for supporting patients who had experienced a medicines-related error is consistent with findings regarding error rates following hospital discharge. Approximately 40% of patients may experience medicines-related errors after discharge from hospital [37, 38]. Learning from medicines-related errors in order to implement methods for their reduction is a current NHS and worldwide healthcare priority [39]. In relation to PMHS, a recent systematic review examined the types of enquiries received to PMHS and found that, on average, 27% of calls are regarding medicines-related errors [40]. Therefore, a PMHS may provide one avenue for reducing medicines-related errors, if the information from such enquiries is developed into recommendations and implemented to improve practice.

Our findings suggest that a consequence of reducing medicines-related errors and improving medicines-related counselling at hospital discharge may be that fewer patients need support with their medicines following hospital discharge. This may result in the number of enquiries to PMHS being reduced. Reducing the need for patients to contact a PMHS after their discharge may help to address one of the key issues of providing a PMHS that was found in our study – that resources are often insufficient. Additionally, providing better medicines-related support to patients earlier in their care pathways could mean that more patients avoid medicines-related issues after discharge, and not just the proactive patients and carers who choose to seek support.

Recommendations for practice

Our findings suggest that recommendations to improve the impact of PMHS must be achievable within a resource-limited context. Therefore, we recommend the following:

PMHS providers could examine the types of calls they receive, and where possible, learn from them and improve practice. Over time, certain enquiries (e.g., those regarding errors, and those received as a consequence of inadequate discharge counselling) may be reduced, which may also reduce the burden upon PMHS providers.

To reduce the cost of manning a PMHS, rather than having a pharmacist answer enquiries, a triaging system would be cheaper and more efficient whereby a pharmacy technician answers enquiries, and forwards more complex ones to a pharmacist.

In order to reduce the cost of promotion, and increase the reach of PMHS to all discharged hospital patients who may require support with their medicines, helpline providers could promote their service for free by ensuring that their helpline number is included within discharge summaries that patients receive.

Relatedly, we recommend that providers of PMHS share their ideas for implementing and maintaining a PMHS within a resource-limited context. This could be co-ordinated by regional MI centres, and published via the UK medicines information network [41]. We also recommend that outputs from all improvement projects are made available by PMHS providers to their senior managers and their hospitals' executive team, in order to show the value and efficiency of providing a PMHS.

Recommendations for future research

High-quality, multi-site research is needed to examine whether the perceived benefits of PMHS described in

this study can be evidenced. Such evidence may result in more NHS Trusts establishing their own PMHS. This is important, since a survey study conducted in 2017 found that only 52% of Trusts in England provided a PMHS [12]. However, evaluation of PMHS services was a critical issue in the present study, with participants describing difficulties measuring the effectiveness and cost-effectiveness of PMHS services. In order to share expertise and resources, and increase the generalisability of findings, we recommend that sites collaborate with one another, for example, within a region. Such studies could be coordinated by regional MI centres.

The views and experiences of both service users' and service providers' are considered important for improving the quality of healthcare services [14]. It would therefore also be advantageous for future research to explore patients' and carers' experiences of using a PMHS, also using qualitative methods. Such an idiographic approach would enable service users themselves to provide a detailed consideration of how and why PMHS may be beneficial, and ways that they may be improved, in order to develop further recommendations for their improvement.

Strengths and limitations

This is the first study to take an idiographic approach to exploring pharmacy professionals' perceptions of PMHS, thereby providing rich and contextualised accounts of PMHS provision that have resulted in recommendations for service improvement and future research endeavours. Additionally, we used RE-AIM, an established evaluation framework, to achieve this [22]. Thus, all five aspects of the impact of interventions, as conceptualised by the developers of RE-AIM, have been incorporated into our data collection and analysis processes. Consideration was also made throughout the study processes to enhance the validity and trustworthiness of our findings.

A limitation of this study is that although we invited pharmacy professionals from all known NHS Trusts that provided a PMHS, pharmacy professionals were still required to opt in to participate. This may have resulted in bias, since the perspectives of the pharmacy professionals who decided not to participate are not represented. Additionally, the sample predominantly comprised pharmacy professionals from acute NHS Trusts, and therefore could have be improved by the addition of pharmacy professionals from other Trust types (e.g., mental health, specialist, and community Trusts).

Conclusion

This qualitative study highlights several potential benefits of PMHS, for both patients and healthcare organisations. However, actually evidencing the benefits of PMHS is perceived to be challenging, such as the difficulty measuring what would have happened had the service not existed, and not having the resources to evidence their effectiveness. Lack of resources (e.g., no specific funding, staffing) was also perceived to impact the implementation, maintenance, and reach of PMHS. We recommend that helpline providers share best practice for providing a PMHS within a resource-limited context. High-quality research is needed to evidence the effectiveness and cost-effectiveness of PMHS, which may help to secure adequate resources for this service in the future.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-05182-w.

Additional file 1. Participant characteristics. Table providing a more detailed account of participant characteristics.

Additional file 2. Interview schedule. Data collection interview schedule.

Abbreviations

PMHS: Patient medicines helpline service; UK: United Kingdom; NHS: National Health Service; RE-AIM: Reach, efficacy/effectiveness, adoption, implementation, and maintenance; MI: Medicines information; GP: General practitioner; A&E: Accident and emergency department

Acknowledgements

We would like to thank the three pharmacists who provided feedback on the interview schedule, and the pharmacy professionals who participated in this study.

Endnotes

1. The English National Health Service (NHS) is organised in to NHS Trusts, which are organisations that provide goods and services for the purposes of health care (e.g., hospital and community services), and each Trust primarily serves a geographical area within England.

Authors' contributions

The study was designed by MW and MJ, with advice from AJ and JS. MW collected all data, conducted the analyses, and drafted the manuscript. All authors read, provided feedback, and approved the final manuscript.

Funding

The lead author was funded by a Graduate School Scholarship provided by the University of Bath. The funder had no role in the study design, the collection, analysis and interpretation of the data, the writing of the report, and the decision to submit the article for publication.

Availability of data and materials

Anonymised transcripts and datasets are available from the University of Bath Research Data Archive to bona fide researchers [43].

Ethics approval and consent to participate

This study was reviewed and approved by the NHS Health Research Authority (IRAS ID: 234481). The study was reviewed by, and received ethics clearance, through the University of Bath Research Ethics Approval Committee for Health (Ref: EP 17/18 138).

Verbal informed consent was obtained from all participants prior to initiating interviews. A verbal recording of consent was deemed to be appropriate by the British Psychological Society for low risk, telephone interview studies [42].

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Received: 11 November 2019 Accepted: 1 April 2020
Published online: 29 April 2020

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7.4 Chapter 7 summary

This chapter presented the findings of a qualitative study exploring pharmacy professionals' experiences and perceptions of providing PMHS. This study expands upon the findings of Study 1, the survey study exploring the provision and operation of PMHS in England. Study 1 found that the availability and promotion of PMHS do not meet national standards, which suggests that this could be a reason for the suboptimal use of this service. The qualitative data presented in this chapter shows that pharmacy professionals perceive the limited availability and promotion of PMHS to be a consequence of limited resources (i.e., being understaffed, and not having specific funding for the service). However, despite this, PMHS are perceived to have a number of benefits, and these benefits accord with those found using survey methods in Study 1. For example, PMHS are perceived to provide a 'safety net' to patients during the transfer of care period, provide reassurance to patients, help to optimise patients' medicines, resolve medicines-related errors, reduce the burden upon other services, and provide the potential to improve hospital services based upon the content of enquiries. Therefore, the perceived benefits of PMHS from the perspectives of pharmacy professionals who provide this service has now been explored using both quantitative and qualitative methods.

The systematic reviews presented earlier in this thesis also established that the perceived benefits of PMHS from the perspectives of service users have only been explored using survey methods. Therefore, the next chapter presents a study using qualitative methods to explore the experiences of service users who use PMHS.

The development of the data collection tool for this study was informed by the RE-AIM framework (3). RE-AIM is a detailed framework, since all five of its dimensions comprise sub-elements that should be explored in order to establish the impact of an intervention or service (4). However, in order to examine all aspects of the RE-AIM framework, both quantitative and qualitative methods are needed, and the perspectives of both service providers and service users are required (4).Thus, although the interview schedule used in this study was informed by the RE-AIM framework, certain aspects of it were excluded because they did not seem relevant for answering the research question for this particular study (e.g., asking

participants about the representativeness of enquirers to PMHS more broadly, and the representativeness of sites that provide a PMHS).

Relatedly, the RE-AIM framework was used to analyse the interview data using framework analysis (FA). FA involves the stages of familiarisation with the data, coding, developing an analytical framework, indexing, charting, and interpretation (5). With framework analysis, there is no rule that the framework used will then become the final themes that are presented (5). So, although RE-AIM was used deductively, during the 'developing an analytical framework' stage, it became apparent later in the analysis that it did not make sense to present the findings in terms of five themes that corresponded to the five dimensions of RE-AIM. For example, each theme had at least two sub-themes, which meant there were over ten sub-themes to report, had this approach been taken. This may have been confusing for the reader. Additionally, whilst conducting the analysis, there were noticeable linkages across the different elements of RE-AIM, which meant that organising the findings across the five RE-AIM dimensions would have ignored these linkages. It made more sense to abandon the RE-AIM framework at the interpretation stage, and to organise the findings into themes that made the most sense to me and my supervisors. During the write-up, where relevant, I tried to show where the different elements of RE-AIM influenced each other. For example, lack of promotion and availability (Implementation) influences the reach of the service, and reach influences the assessment of its effectiveness (e.g., low numbers result in a poor number of satisfaction survey responses).

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Chapter 8: Service users' experiences of contacting NHS patient medicines helpline services: A qualitative study.

8.1 Overview of Chapter 8

As established in the systematic review examining the effectiveness of PMHS, to date, studies of PMHS have predominantly examined the views of service users using user satisfaction surveys. The aim of this novel qualitative study was to address a gap in the literature by idiographically exploring patients' and carers' experiences of using a PMHS, their benefits, and ways that they can be improved. Through learning about patients' and carers' experiences of PMHS, we aimed to make suggestions to improve how helplines are operated. In particular, this study addressed the following research question: *What are patients' and carers' experiences of contacting an NHS PMHS?*

This study has been submitted for publication and is currently under review. Therefore, the submitted manuscript is presented. Following the manuscript is a brief summary of the study's findings, and a description of how the study fits within the wider context of the PhD.

8.2 Statement of authorship

<table>
<tr><td colspan="4">This declaration concerns the article entitled:</td></tr>
<tr><td colspan="4">Service users' experiences of contacting NHS patient medicines helpline services: A qualitative study.</td></tr>
<tr><td colspan="4">Publication status (tick one)
Draft manuscript [ ] Submitted [ ] In review [ ] Accepted [√] Published [ ]</td></tr>
<tr><td>Publication details (reference)</td><td colspan="3">Williams M, Jordan A, Scott J, Jones M. Service users' experiences of contacting NHS patient medicines helpline services: A qualitative study.</td></tr>
<tr><td colspan="4">Copyright status (tick the appropriate statement)
I hold the copyright for this material [√] Copyright is retained by the publisher, but I have been given permission to replicate the material here [ ]</td></tr>
<tr><td>Candidate's contribution to the paper (provide details, and also indicate as a percentage)</td><td colspan="3">The candidate contributed to / considerably contributed to / predominantly executed the…

Formulation of ideas: I formulated the ideas for this study (90%), with support from my supervisory team (10%).

Design of methodology: I designed the methodology for this study (90%), with support from my supervisory team (10%).

Experimental work: I carried out the study (i.e., collected and analysed the data) (100%).

Presentation of data in journal format: I wrote the study for publication (85%), with support from my supervisory team (15%).</td></tr>
<tr><td>Statement from Candidate</td><td colspan="3">This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.</td></tr>
<tr><td>Signed</td><td>  </td><td>Date</td><td>02/05/2020</td></tr>
</table>

8.3 Submitted manuscript

The manuscript presented on the following pages is as it was drafted and submitted for review.

Table 1 in the submitted manuscript represents Table 8.1 of this thesis.

Table 2 in the submitted manuscript represents Table 8.2 of this thesis.

Table 3 in the submitted manuscript represents Table 8.3 of this thesis.

Supplementary file 1 in the submitted article represents Appendix 11 of this thesis.

Supplementary file 2 in the submitted article represents Appendix 12 of this thesis.

Abstract

Objectives: Patient medicines helpline services (PMHS) are available from some National Health Service (NHS) Trusts in the UK to provide medicines information to hospital patients and carers. To date, studies of PMHS have examined the views of service users via satisfaction surveys. This study used qualitative methods to explore service users' experiences of using a PMHS, including perceived benefits and areas for improvement.

Methods: This study was conducted across seven NHS Trusts in England. Forty users of PMHS were individually interviewed over the telephone. Interviews were audio-recorded, transcribed verbatim, and analysed using Braun & Clarke's inductive reflexive Thematic Analysis. Ethical approval was obtained before study commencement.

Results: Participants predominantly called a PMHS for themselves (82%). Two main themes were generated. *Theme 1: Timeliness*: PMHS provide support during the uncertain transition of care period from hospital to home, when patients and carers often feel vulnerable because support is less available. PMHS met service users' needs for timely and easily accessible support, and quick resolution of their issues. PMHS could be improved with staffing beyond typical work week hours, and by having staff available to answer calls instead of using an answerphone. *Theme 2: PMHS are best-placed to help*: PMHS were perceived as best-placed to answer enquiries that arose from hospital care. Service users felt reassured from speaking to pharmacy professionals, and PMHS were perceived as the optimal service in terms of knowledge and expertise regarding medicines-related questions. However, several participants were initially unaware that their PMHS existed.

Conclusions: PMHS are perceived to be a valuable means of accessing timely medicines-related support when patients and carers may be feeling particularly vulnerable. However, their availability and promotion could be improved. We recommend that providers of PMHS consider whether this is achievable, in order to better meet the needs of service users.

Keywords: Patients, carers, service users, medicines information, drug information services, patient medicines helpline services, hospital discharge, National Health Service, qualitative, thematic analysis.

Strengths and limitations of this study

- This is the first study to adopt an idiographic approach to exploring service users' experiences of using patient medicines helpline service.
- Participants were recruited from a geographically diverse range of NHS Trusts (n=7) across England.
- Providers of the service acted as gatekeepers to participants, which may have resulted in participant selection bias.
- The sample primarily comprised service users from acute NHS Trusts, and therefore could have been improved by additional service users from other Trust types (e.g., specialist and mental health).

BACKGROUND

Many patients leave hospital with gaps in their knowledge about their medicines,(1-6) and a sizeable number of patients subsequently experience medicines-related errors and require support with medicines-related problems.(7-14) Consequently, hospital discharge may be a confusing and/or risky period for patients who have recently experienced changes to their medicines.

Patient medicines helpline services (PMHS) have been set up at many National Health Service Trusts (NHS) in the United Kingdom with the aim of providing medicines-related support to recently discharged hospital patients and their carers. The first PMHS was set up in the UK in 1992, and a survey study conducted in 2017 reported that 52% of NHS Trusts provided a PMHS.(15) Providing a PMHS accords with World Health Organisation (WHO) policy, which states that offering information on medicines via Medicines Information (MI) centres, and providing public education about medicines, are essential interventions to promote the rational use of medicines.(16)

In line with healthcare quality improvement approaches, services are likely to be improved by seeking to understand the experiences of service users.(17) In order to ascertain service users' views and experiences of PMHS, quantitative satisfaction survey studies have been conducted, whereas qualitative studies have not.(18) The results of such survey studies suggest that service users typically consider PMHS to be beneficial.(18) For example, a recent systematic review found that satisfaction ratings are excellent, the advice received is reported to be usually followed, and users report several positive outcomes, such as feeling reassured, and improved health.(18) However, a limitation of survey studies is that surveys include questions that are important to the researcher, rather than allowing participants to provide in-depth information that is important to them. Relatedly, survey answer options do not permit participants to respond in-depth using their own words. To enable service users to provide a detailed consideration of how and why PMHS may be beneficial and how they could be improved, an idiographic approach is needed.

Whereas the nomothetic approach is considered useful for making generalisations about groups of individuals in order to make assumptions about populations, the idiographic approach is considered useful for exploring individuals' lived experiences of a phenomenon.(19) Idiography is concerned with exploring the in-depth experiences of particular individuals in particular contexts, and qualitative methods are considered appropriate for collecting rich data in order to achieve this.(19) Consequently, our study sought to address an important knowledge gap by being the first study to take an idiographic approach, and use qualitative methods, to explore service users' experiences of PMHS.

Aim

The aim of this novel qualitative study was to explore patients' and carers' experiences of using a PMHS, their benefits, and ways that they can be improved. Through learning about patients' and carers' experiences of PMHS, we aimed to suggest improvements to how PMHS are delivered. In particular, this study addressed the following research question: *What are patients' and carers' experiences of using an NHS patient medicines helpline service?*

METHOD

Study design

The authors adopted the epistemological position of pragmatism, in order to develop recommendations for service improvement for the benefit of users of PMHS. Pragmatism uses appropriate methods for solving practical problems, with an emphasis upon the usefulness of research.(20) Pragmatism has become increasingly popular in health research, since its aim is to produce findings that are of benefit to service users.(20-22)

For transparency, the study authors comprise three University academics with PhDs (one male, two female) and one PhD student with an MSc (male). All study authors have an interest in pharmacy practice, health services research, and/or health psychology. One author (MJ) has prior experience of managing a PMHS for an NHS Trust in England.

Participants and recruitment

Recruitment was conducted via seven NHS Trusts from different regions within England: four acute Trusts, one mental health Trust, one specialist Trust, and one community Trust. Initially, four Trusts were recruited, one of each type. Additional Trusts of all types were subsequently recruited in order to ensure that our sample target was met, and to enhance the diversity of experiences included in the analysis. However, only three additional acute Trusts agreed to take part. Pharmacy professionals who provided the PMHS at sites acted as gatekeepers to the recruitment of participants, with each site recruiting participants over a six-month period.

Eligible participants were required to be either a patient, or a patient's non-professional carer, who recently used a PMHS provided by an NHS Trust within England for the purpose of seeking support regarding medicines. Participants were also required to be aged 16 years or older, fluent in English, and available to participate in a telephone interview within one month of having used the PMHS. Participants were excluded if, in the pharmacy professional's judgement, taking part would likely cause distress to the service user. Pharmacy professionals were also required to exclude service users who stated they were (or were considering) making a complaint against the Trust, and if the service user was a healthcare professional to the patient.

Invitations to participate in the study were sent from Trusts to all helpline enquirers who agreed to receive study information at the end of their call to the PMHS. After reading the study participant information sheet, interested individuals opted in by contacting the research team via telephone or email in order to participate. Prior to participation, interested individuals were informed as to the purpose of the study and what participation entailed, including key ethical issues (e.g., data storage and confidentiality). Interested individuals also had the opportunity to ask questions about the study.

Our estimated sample size was based upon that of published qualitative studies of service users' experiences of healthcare services, and recommendations in literature.(23) In relation to such guidance, we aimed to conduct forty interviews.

The sample size was not based upon reaching data saturation. The concept of data saturation has been challenged as a means of identifying the appropriate number of participants to include in a study.(24) For example, it has been suggested that data may never be truly saturated, since there could always be potential codes and themes to be identified.(25)

The first forty individuals who contacted the study team and met the study eligibility criteria were recruited into the study. Prior to data collection, verbal informed consent was obtained from each participant via telephone, which is appropriate for low risk, telephone interview studies.(26)

Data collection

Semi-structured interviews were chosen as the data collection method in order to provide flexibility through the use of probes and unplanned questions. This increased the potential for producing richer data compared with other approaches that were considered, such as a qualitative survey.(23) Data were collected via telephone, enabling participants throughout England to be easily interviewed. Evidence suggests that telephone interviews can lead to rich data, provided that interviewers ensure that participants' needs are understood and respected.(27, 28) Consequently, care was taken to ensure that participants were comfortable being interviewed over the telephone, and that they also felt able to pause the interview at any time and to ask clarification. Each participant was interviewed once.

During the same telephone call as the interview, but before the interview was conducted, the following background information was collected from participants: Name of NHS Trust contacted, date of PMHS contact, whether they had previously used a PMHS. Patients were also asked whether they were an inpatient or outpatient for their recent period of care, and the number of prescribed medicines they were prescribed at the time of the PMHS contact. Carers were also asked their relationship to the patient who the PMHS contact was regarding.

Separate interview schedules were developed for patients and carers (see Supplementary file 1 for the interview schedules). Table 1 provides a summary of the interview topics (e.g. what the patient/carer found helpful and unhelpful about

their experience of contacting the PMHS). The interview schedules were broadly similar, although, for ethical reasons, the carer version did not contain questions that would have resulted in them providing personal information about the individual in their care. The aim of the interview with carers was to explore whether the PMHS met their needs as a carer seeking information. Both schedules comprised open-ended questions, and were developed in accordance with established conventions for semi-structured interviewing.(23, 29-31)

Table 1. Topics for the interviews with service users

Topics for interviews with service users
1. Why the patient/carer contacted the helpline service, including what their question or concern was, the perceived seriousness of the issue, whether they considered any other sources of medicines information, and their decision-making process for choosing to use the helpline service.
2. What the patient/carer found helpful and unhelpful about their experience of contacting the medicines helpline service.
3. What impact the patient's/carer's use of the service has had (e.g., Was the advice followed? If so, what were the outcomes of this? If the advice was not followed, what were the reasons for this?).
4. Whether there were any negative consequences of using the helpline service.
5. How the patient/carer felt about the medicines now, compared to before the helpline contact.
6. How the patient/carer felt about the hospital and NHS Trust now, compared to before the helpline contact.
7. What the patient/carer would have done had the helpline service not been available, and why.
8. Whether the patient/carer sought any other sources of medicines-related information or support following their use of the helpline service, and if so, why.

During data collection, the interview schedules served as flexible guides for interviews, enabling participants to discuss aspects of their experiences of using a PMHS that were important to them.

During the same telephone call as the interview, but after their interview had been conducted, the following background data were collected from each participant: age, gender, ethnicity, and current occupational status.

All interviews were conducted by a trained interviewer (MW), audio-recorded, and transcribed verbatim.

Data analysis

Braun and Clarke's inductive reflexive thematic analysis (TA) was used to analyse the qualitative interview data.(32, 33) TA is a systematic, rigorous and transparent technique for organising, describing, and interpreting data, which has been used within health research to explore patients' experiences of healthcare services.(34-36) Braun & Clarke's TA was chosen instead of other thematic methods, since it provides a straight-forward step-by-step process for conducting a thorough and transparent analysis.

Analysis involved the following stages, as outlined by Braun and Clarke: familiarisation with the data, generating initial codes, developing themes, reviewing themes, defining and naming themes, and writing the analysis.(23, 32) Individual interview transcripts were uploaded into NVivo version 12,(37) which was used for generating initial codes and developing and reviewing themes. The only deviation to the TA stages was that Iterative Categorisation (IC) was used in place of the defining themes stage.(38) The choice to use IC was made in order to increase transparency and rigour. IC is also a systematic, rigorous and transparent technique, which can be used to support a range of analytical techniques, including TA .(38) IC leaves a clear audit trail, which provides a route back to the coded data (see Neale for further details).(38)

Patient and public involvement

The study design and documents (participant information sheet and interview schedules) were reviewed by six members of the public who were either recent hospital patients or carers. Refinements to the documents were made based upon their feedback. Patients/the public were not involved in the recruitment of participants, nor dissemination of findings.

Establishing quality in qualitative research

Yardley's criteria for demonstrating the quality of qualitative research were met (39). For *sensitivity to context*, previous literature was reviewed in preparation for the study, and we endeavoured to recruit participants from several different NHS Trusts. For *commitment and rigour*, TA and IC stages were followed, including Braun & Clarke's 15-point guidelines on conducting TA,(23) and a 'paper trail' approach was used. Also, credibility checks were conducted, where each stage of the analysis was checked by another member of the research team to verify that the identified codes and themes were appropriate. Additionally, the consolidated criteria for reporting qualitative research (COREQ) and the standards for reporting qualitative research (SRQR) were followed.(40, 41) For *coherence and transparency*, the study results are grounded in example quotations from the raw data. A reflective diary was used throughout the process of data collection and analysis, to record thoughts about each interview, contextual features that may have influenced interviews, and/or any ways that interviews could have been improved in order to enhance subsequent interviews. Additionally, the authors have disclosed their positions regarding the research topic. For *impact and importance*, the study findings were used to develop recommendations for improving the provision of PMHS.

RESULTS

Participant characteristics

Table 2 provides an overview of participant characteristics (see Supplementary file 2 for anonymised information regarding each participant). Participants were predominantly, female, elderly, had used a PMHS regarding

themselves, and had used a PMHS that was based at an acute Trust. Table 3 provides an overview of the types of enquiries that participants made to the PMHS.

Table 2. Participant characteristics

Characteristic		Participants (*n* = 40)
		n (%), or mean years (SD; range)
Type of enquirer	Patient, calling for self	33 (82%)
	Carer / calling on behalf of patient	7 (18%)
Type of patient [a]	Inpatient	17 (52%)
	Outpatient	12 (36%)
	Member of the public	4 (12%)
Type of carer [b]	Spouse or partner of patient	5 (71%)
	Parent of patient	1 (14%)
	Son or daughter of patient	1 (14%)
No. medicines currently prescribed [a]	Zero to 4	11 (33%)
	5 to 9	19 (58%)
	10 or more	3 (9%)
Gender of enquirer	Male	17 (42%)
	Female	23 (58%)
Age of enquirer (years)		68 (9.87; 44 to 85)
Ethnicity of enquirer	White or White British	38 (95%)
	Asian or Asian British	1 (3%)
	Mixed race	1 (3%)
Occupational status of enquirer	Retired	30 (75%)
	Employed	4 (10%)
	Unemployed	4 (11%)
	Carer and/or homemaker	2 (5%)
Has enquirer used PMHS in the past?	No	34 (85%)
	Yes	6 (15%)
NHS Trust type where PMHS was used	Acute 1	23 (57.5%)
	Acute 2	6 (15%)
	Acute 3	6 (15%)
	Acute 4	3 (7.5%)
	Mental health	1 (2.5%)
	Specialist	1 (2.5%)
	Community	0 (0%)

Note. Abbreviations: NHS = National Health Service; PMHS = patient medicines helpline service.

[a] Data collected only from participants who were patients

[b] Data collected only from participants who were carers

*Table 3. Types of enquiries made by study participants (*n = *40)*

Enquiry type	n (%)

Administration or dosage	10 (25%)
Interaction	9 (23%)
Supply	7 (18)
Medicines-related error [a]	6 (15%)
Side effects	6 (15%)
Storage	2 (5%)

[a] Incorrect medicine prescribed (*n* = 3); missing medication (*n* = 2); discharge paperwork not sent to primary care, causing a delay to receive medication (*n* = 1)

Interview duration

Interview duration ranged from 12 to 66 minutes (mean = 25 minutes).

Overview of themes

Two main themes were generated from the analyses: *Timeliness,* and *PMHS are best-placed to help*. *Timeliness* identifies that service users often feel vulnerable after discharge from secondary care, and that service users want quick access to support when they need it, from pharmacy professionals who are available to help them. This is what PMHS have the potential to provide, although their availability could be improved. *PMHS are best-placed to help* reveals that PMHS may reduce the burden upon other healthcare services, and that PMHS are considered to be the best place to access medicines-related support pertaining to hospital care, from pharmacy professionals with expert knowledge. Pharmacy professionals were considered to have positive personal qualities that helped to reassure service users. However, although PMHS are considered best-placed to help, service users' awareness of the existence of PMHS could be improved.

Theme 1: Timeliness

Vulnerable after discharge

Participants described feeling vulnerable after leaving hospital, and in need of support during this transition of care period. Reasons for feeling vulnerable after leaving hospital included being in recovery, feeling isolated, being house-bound, experiencing a medicines-related error (e.g., a missing medication), being discharged with multiple medicines and feeling confused, and realising that they had not asked important questions during discharge. The PMHS was perceived to fulfil this important service gap.

"If you've been discharged from hospital, for instance, you're given a bunch of medicines, it's explained to you, and perhaps you don't absorb it all completely… It probably just doesn't quite go in until you come home… and then you think "Ah. Perhaps I should've asked this question." In which case, if you've got something like this helpline, it's invaluable." (P11, Male, Patient)

Accessing help

Pertaining to feeling vulnerable after leaving hospital, participants perceived the situation as stressful, and spoke of the need for immediate help with regards to medication advice. In order to reduce this stress, it was therefore important to be able to access support quickly (i.e., no answerphone or additional buttons to press to get through), and to also have the situation resolved as soon as possible. This is what the PMHS typically enabled.

"I was relieved, actually, to have somebody to talk to immediately that could help me within a short space of time." (P5, Female, Patient)

Participants spoke of the importance of the method of accessing the PMHS, and that the telephone was vital for accessing the service quickly, compared to accessing the service via email. Access methods were often described in relation to participants' perceived severity of the situation (i.e., email would be useful for

situations where help was not needed immediately).

"I think it depends on the urgency of the situation… Because of this situation, [telephone access] was great. It was immediate… but if it wasn't a vital thing, then yes…I could just email it through thinking "I don't even need it today, this minute, but in the next couple of days would be helpful."" (P32, Female, Carer)

Relatedly, some participants commented that potential access options, such as online chat or a mobile phone app, would increase their stress.

"I'm not that keen on technology. At a time when I felt really stressed out, I would've had an added stressor, having to work out how to do it. So, for me, it's very comforting, because I'm very familiar with the telephone [laughs]." (P10, Female, Patient)

However, participants felt that having more than one method of accessing support is useful, such as telephone and email. Several participants considered the access options of email, online chat, and mobile phone app to likely be preferable for younger service users.

Availability of help

Participants described how contacting the PMHS was likely to lead to a quicker resolution in comparison to other sources of support (e.g., their GP, a local pharmacy, NHS 111, or another hospital contact). This was another reason why participants typically contacted the PMHS in the first instance.

"I was waiting to hear back from the surgery, because I left it with the receptionist at the surgery… But actually, I only got a call from the surgery this morning. And this was resolved [by the PMHS], you know, last week." (P16, Female, Patient)

Although most participants described their PMHS as timely, some were concerned about needing the service when it was unavailable (e.g., evenings and weekends, to support patients who get discharged out-of-hours, and people who are unable to contact the service during typical work hours).

"Seven days a week would improve it. If you were discharged on the Friday night, being in the situation I was in, I would've been very concerned." (P9, Female, Patient)

Additionally, only one participant had a negative experience of contacting a PMHS, when they contacted the service for a second time. Here, the helpline team were not available to take the call. The participant left a message on the PMHS answerphone and was not called back.

"I'm wondering if… a vulnerable patient was calling hoping to get some kind of reassurance,… and left a message and they weren't called back, they would mistrust this service." (P6, Female, Patient)

Theme 2: PMHS are best-placed to help

Reduced burden upon other services

Participants considered their PMHS to be best-placed to help for several reasons. Primarily, participants spoke of the importance of returning to the place where they recently received care, rather than seeking advice elsewhere. Many participants felt that they would contact the hospital anyway, had the PMHS not existed.

"*As far as I was concerned. I'd just left the hospital, so I reckoned they [PMHS] would know."* (P28, Female, Patient)

There was recognition that contacting the PMHS could reduce the burden upon other healthcare services, or that queries may have gone unasked, since some

participants described not wanting to burden other healthcare services. PMHS providers were perceived as having more time to answer queries compared to other HCPs, particularly hospital consultants and GPs.

"Hospitals and doctors are extremely busy, and some of the queries you might have might be very trivial, and take up time, which is not the best use of the medical practitioners' time. Some of those issues, if you can deal with a call to this helpline, then I think it's in everybody's best interest." (P31, Male, Patient)

A source of expertise

Participants spoke of the PMHS having the knowledge and resources to deal with enquiries that other HCPs would not necessarily have (e.g., access to medical records; an overview of their multiple health conditions and medicines regimen).

"There's no point ringing up the doctor. Because they aren't specialised in all this treatment, you know. So that's why we rang the [PMHS]." (P1, Female, Carer)

Relatedly, participants described the benefit of speaking to a pharmacy professional regarding their medicines, since pharmacists are experts about medication and their advice can be trusted. Participants often described this as providing them with the reassurance needed to take their medicines as advised, particularly when taking multiple medicines, when the potential for mistakes is increased.

"To make sure that whatever you're proposing to do has at least been under the eye of a pharmacist, makes you feel reassured that you're not doing anything that you shouldn't." (P21, Male, Patient)

Positive personal qualities

Participants also spoke of helpline staff as having positive personal qualities, which were important for providing them with reassurance at a time when they felt

anxious. Several participants compared the positive experience with the helpline staff to less positive experiences with other HCPs (e.g., their GP). Positive personal qualities of helpline staff included being professional, calm, compassionate, down to earth, having good listening and communication skills, being knowledgeable and confident, being thorough, going above and beyond what they wanted, not being dismissive, and working with the patient to devise a plan to support them.

"The person who I dealt with, she listened, she was compassionate, she normalised how I was feeling, and then in order to help alleviate the distress that I felt she made a plan that would reduce the distress that I was feeling. And it was a really really positive experience." (P37, Male, Patient)

Helpful but hidden

Although PMHS were considered best-placed to help, awareness of the service was sometimes poor. A number of participants described how they were not initially aware that the PMHS existed (e.g., they called the hospital and were transferred to the PMHS). There was recognition that PMHS should be promoted more, since they are considered beneficial and could help a greater number of patients.

"I wasn't aware it was available… So I think the more that they can let people know that the service is available, the better." (P36, Female, Carer)

Suggestions for improving promotion of PMHS included pharmacy professionals visiting wards to tell patients about it, putting posters up around the hospital and in the local area (GP surgeries, local pharmacies), and advertising within discharge summaries. However, one participant struggled to find the contact details within their discharge summary, and was initially unsure what the service provided because the promotion was unclear.

"Almost put a bit more higher priority… Because it was buried along in page three or five. I wouldn't have known how I could use that service, or if it was a priority I could use them, or whether I should try other routes before I use them." (P32, Female, Carer)

DISCUSSION

This study explored forty service users' experiences of using an NHS PMHS. Two themes were identified during the analysis: *Timeliness,* and *PMHS are best-placed to help.* The findings illustrate how PMHS meet patients' and carers' needs for timely and easily accessible support, and for enquiries to be quickly resolved. However, PMHS may not always be considered a timely source of support, since the service is not available all the time. PMHS could therefore be improved by being available during evenings and at weekends. Additionally, providing a PMHS with an answerphone will mean that service users will experience a delay to receive help, and there may be a risk that messages are missed. PMHS were perceived to be uniquely placed to answer medication queries that arose from hospital care, and were more positively viewed as approachable and valuable when compared with other sources, such as GPs. However, several participants were initially unaware that the service existed, and so, increasing the promotion of PMHS would ensure that more patients have access to timely help when it is needed. Relatedly, increasing the promotion of PMHS will only be useful if the promotional materials are clear as to who the service is for, and what the service provides.

Our findings accord with those of a recent systematic review and a literature review that examined the evidence regarding the effectiveness of medicines information services for patients and the general public, both within the UK and internationally.(18, 42) Based upon survey study findings, the systematic review concluded that such services are typically perceived positively by service users (e.g., satisfaction ratings are excellent), and users report several positive outcomes such as feeling reassured.(18) Our qualitative study found that PMHS provide reassurance to service users during the transition of care period when service users may be feeling particularly vulnerable. Their anxieties were alleviated by having quick access to an expert who had the skills to address their enquiries efficiently and compassionately.

Our findings also are consistent with two survey studies examining the provision of PMHS in the UK.(15, 43) The most recent of these was conducted in 2017, and surveyed all NHS Trusts in England in order to examine whether Royal Pharmaceutical Society endorsed national standards for providing a PMHS were being met.(15, 44) This survey identified that both the availability and promotion of PMHS were below standard. For example, out of 117 Trusts that provided a PMHS, only 57% reported that their PMHS was available for eight or more hours per day, and only 7% reported that their PMHS was available out-of-hours, such as during evenings and weekends. Additionally, only 40% of Trusts used promotional material describing PMHS access times and the types of enquiries that patients/carers can make. Under-promotion was also identified as an issue in a recently conducted qualitative study exploring thirty-four pharmacy professionals' perceptions of providing PMHS.(45) Under-promotion was perceived by pharmacy professionals as a reason why PMHS are underused. Additionally, some pharmacy professionals described how their PMHS is under-promoted for fear of not being able to cope with the demand due to lack of resources to adequately deliver the service. Promotion of PMHS is important because if patients do not know that the service exists, they cannot utilise it, thus the opportunity to resolve medicines-related issues is missed. This may result in harm to patients. An evaluation of 500 calls to one PMHS at an acute NHS Trust found that 48% of issues may have resulted in patient harm had professional information from the helpline not been available.(46)

Recommendations for practice

Study findings suggest that to better meet the needs of the service users, the provision of PMHS could be improved by extending their opening hours so that they are available during evenings and weekends. Providers should also ensure that helpline staff are available to answer the telephone rather than using answerphones. The promotion of the service could be improved to increase knowledge of the service among patients and carers. Such promotion could include ward pharmacists telling their patients and patients' carers about the PMHS during ward rounds, and by advertising the PMHS clearly in patients' copies of their discharge summaries. However, we appreciate that the above recommendations may be challenging since PMHS are often established without funding and are often provided within a resource-limited context.(43, 45) Because our findings described in this study and in a recently conducted systematic review suggest that PMHS can have several benefits for

patients,(18) budget holders/commissioners should consider whether they should fund new PMHS. This is important, since a survey study conducted in 2017 reported that only 52% of NHS Trusts provided a PMHS.(15)

Recommendations for future research

Future research is needed to better understand the needs of patients and carers when contacting a PMHS, particularly pertaining to service availability, methods of access, and promotion. One option could be to conduct a large, prospective, multi-site mixed methods survey, with enquirers of all ages, in order to enhance the generalisability of the findings. Another option could be to conduct a discreet choice experiment in order to elicit potential service users' preferences regarding the provision of PMHS, such as the availability, access, and promotion of the service. Further research is also needed to explore the experiences of patients and carers who have problems or queries regarding medicines following hospital discharge, yet do not contact their Trust's PMHS. This may result in additional recommendations to improve the awareness and use of PMHS.

Strengths and limitations

This is the first study to take an idiographic approach to exploring service users' perceptions of PMHS, thereby providing rich and contextualised accounts of PMHS use that have resulted in recommendations for service improvement and future research endeavours. Service users were recruited from seven NHS Trusts from different regions within England in order to include a broad range of experiences of PMHS use. Additionally, consideration was made throughout the study to enhance the validity and trustworthiness of the findings. However, providers of the service acted as gatekeepers to participants, which may have resulted in selection bias. Furthermore, the sample predominantly comprised service users from acute NHS Trusts, and therefore could have been improved by the addition of service users from other Trust types (e.g., mental health, specialist, and community Trusts). Finally, the sample may also be limited since participants had already chosen to contact a PMHS and may therefore be likely to hold positive views about telephone helplines.

Conclusion

PMHS are seen as a valuable means of easily accessing timely medicines-related support during a transfer of care period, when patients and carers may be feeling particularly vulnerable. PMHS were perceived as best-placed to answer enquiries that arose from hospital care. PMHS were also perceived as the optimal service in terms of knowledge and expertise with regard to answering questions about medications. However, the availability and promotion of PMHS could be improved. We recommend that providers of PMHS consider whether this is achievable, in order to better meet the needs of service users.

LIST OF ABREVIATIONS

PMHS: patient medicines helpline service; UK: United Kingdom; NHS: National Health Service; MI: Medicines information; GP: general practitioner.

DECLARATIONS

Acknowledgements

We would like to thank the pharmacy professionals from the seven NHS Trusts who supported the study by being participant identification sites, and the patients and carers who took the time to participate in this study.

Contributors

MW designed the study, collected all data, conducted the analyses, and drafted the manuscript. AJ provided advice regarding study design, including expertise in qualitative methods, and read, provided feedback and approved the final manuscript. JS provided advice regarding study design, and read, provided feedback and approved the final manuscript. MJ provided advice regarding study design, and read, provided feedback and approved the final manuscript.

Funding

The lead author was funded by a Graduate School Scholarship provided by the University of Bath. The funder had no role in the study design, the collection, analysis and interpretation of the data, the writing of the report, and the decision to submit the article for publication.

Competing interests

The authors declare that they have no competing interests.

Patient consent for publication

This article does not contain personal medical information about an identifiable living individual. Therefore, patient consent for publication was not required.

Ethics approval

This study was reviewed and approved by the London – Brighton & Sussex Research Ethics Committee, and the NHS Health Research Authority (IRAS ID: 233726). The study also received ethical clearance through the Research Ethics Approval Committee for Health of the University of Bath.

Data availability statement

Anonymised transcripts and datasets are available from the University of Bath Research Data Archive (47).

8.4 Chapter 8 summary

This chapter presented the findings of the final study of this doctoral research. This was a qualitative study exploring service users' experiences of contacting PMHS. The two themes generated from the analysis show that service users value having timely access to pharmacy professionals who they consider are best-placed to help them at a time when they may be feeling particularly vulnerable and anxious regarding their medicines. However, the findings also suggest that the availability and promotion of PMHS could be improved. This accords with previous findings from studies comprising this doctoral research. For example, Study 1 used survey methods to establish that the promotion and availability of PMHS in England are not meeting national standards for operating a PMHS. Additionally, the qualitative study of pharmacy professionals' perceptions of PMHS showed that pharmacy professionals perceived the promotion and availability of their PMHS to be suboptimal, and attributed this to not having sufficient resources to provide the service.

The development of the data collection tool for this study was, to some extent, informed by the RE-AIM framework (48). RE-AIM comprises five dimensions (Reach, Effectiveness, Adoption, Implementation, and Maintenance), and all five of its dimensions comprise sub-elements that should all ideally be explored in order to establish the impact of an intervention or service (49). However, depending on the study being conducted, it may not be appropriate to examine all aspects of RE-AIM. For example, in order to examine all aspects of the RE-AIM framework, both quantitative and qualitative methods are needed, and the perspectives of both service providers and service users are required (49). Service users will only be able to comment upon those aspects of the intervention or service that they experienced as a user. Therefore, they may be well-placed to comment upon the use of the service in order for recommendations to be made to improve its implementation. They will also be able to describe their experiences of the effectiveness of the service. However, they are not well placed to answer questions pertaining to the adoption and reach of the service, since these aspects have nothing to do with their experience of using one PMHS on one occasion. They could, however, describe the longer-term effect (if any) that the service had upon them. This is a sub-element of the *Maintenance* aspect of the framework. However, since participants in this qualitative study were interviewed within one month of

using the helpline service, it was not possible to ask questions about the longer-term effect that the advice may have had upon them. Therefore, the focus of this study in terms of the RE-AIM framework was on the *Effectiveness* and *Implementation* aspects only. Relatedly, the Implementation aspect primarily focused upon the national standards for providing a PMHS, namely the access, availability, and promotion of the service. However, participants were given the opportunity to describe their experiences of using the helpline service beyond these three aspects, so that a broader understanding of their use of PMHS could be established.

A limitation of this study is that helpline providers acted as gatekeepers to study participants. This likely resulted in selection bias. Helpline providers had the opportunity to not invite enquirers if they felt that inviting them would be inappropriate (e.g., if the enquirer was upset, or angry). However, interviewing such individuals about their experiences of the helpline services could have resulted in novel data, and may have resulted in additional recommendations for improving these services. Ideally, *all* individuals who contacted the seven PMHS during the six-month recruitment period would have been invited to participate in this study. Prior to starting this study, discussion with potential research sites made it clear that they would not participate in the study without this exclusion criteria. Therefore, our research question could only be investigated by allowing helpline providers to choose who to invite.

The theme ‘PMHS are best-placed to help’ shows that participants perceived the helpline services to be the most appropriate place to receive help for the enquiries that they had. This was often in comparison to other options, such as their GP, a consultant at the hospital, or the ward where they stayed during their admission. Participants felt that calling the PMHS resulted in them having more time to discuss their issue (compared to, for example, contacting their GP), and that the helpline pharmacists based at the hospital were best-placed to answer questions about medicines that were changed or started as a result of a hospital stay. They were seen as a source of expertise. Additionally, participants were very complimentary about the care they received during the helpline call. All participants described the person who helped them positively, using words such as compassionate, kind, caring, empathic, dedicated, knowledgeable, thorough, and

skilled. However, it is unknown as to whether helpline providers are typically like this, or whether participating in the study modified their behaviour to increase the likelihood that participants in the study would be complimentary of the service and the helpline provider.

Since this was the final study of the doctoral research, the next and final chapter of this thesis provides a general discussion of the five studies, and their contribution to the wider literature around PMHS.

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Chapter 9: General Discussion

9.1 Overview of chapter

This chapter provides a general discussion of the research conducted for this doctorate, which examines the impact of NHS patient medicines helpline services (PMHS) upon service users and healthcare organisations using the RE-AIM evaluation framework. The chapter begins with a summary of the main findings, in order to answer the research question. Next, the main study findings are discussed in relation to relevant literature pertaining to medicines information services, and pharmacy services research more broadly. This section ends with a discussion of the potential future direction of MI services for patients and carers. Following this, the strengths and limitations of the research are discussed, along with potential avenues for future research. Finally, the chapter ends with recommendations for clinical practice, and concluding thoughts.

9.2. Summary of findings from this doctoral research

The aim of this research was to address the following question: *What is the impact of National Health Service patient medicines helpline services upon service users and healthcare organisations?* To examine the impact of PMHS, the RE-AIM evaluation framework was used throughout this research (1). The RE-AIM framework conceptualises the impact of an intervention as the product of its reach, effectiveness, adoption, implementation, and maintenance.

The findings across all five studies suggest that PMHS have the potential to provide timely medicines-related support to patients and carers following discharge from hospital. A systematic review of the literature regarding enquiries to PMHS show that this service provides information pertaining to medicines such as adverse effects, administration and dosage, interactions, and efficacy. PMHS also support patients and carers by correcting medication errors (e.g., providing supplies of medications missing from discharge prescriptions). PMHS are perceived as effective and valued from the perspectives of pharmacy professionals who provide them, and patients and carers who use them. However, the evidence generated from this research regarding the effectiveness of PMHS is limited by primarily consisting of subjective experiences and perceptions (e.g., survey and interview

data) rather than hard outcomes (e.g., readmission rates, symptoms and disease recurrence). The findings from this research also show that, despite their perceived benefits, the insufficient adoption, implementation, and reach of PMHS hinders their overall impact. The insufficient adoption, implementation and reach of PMHS are perceived to be consequences of limited resources and staffing. For example, limited resources and staffing are barriers to providing a PMHS, and also negatively affect the availability and promotion of extant PMHS. This means that PMHS may not be able to help all of the people who want to seek support regarding their medicines following hospital discharge. However, despite limited resources and staffing, the findings from this research suggest that once adopted, PMHS are likely to become a relatively stable service for NHS Trusts. This may be a consequence of PMHS being perceived by their providers as being beneficial and valued, and providing job satisfaction.

Based upon the findings from this research, which primarily comprise survey and qualitative data, it cannot be concluded that PMHS are effective in terms of hard outcomes. Nor does the research show that good implementation (i.e., strict adherence to the national standards) result in improved outcomes. Thus, the findings from this research are unlikely to result in all NHS Trusts providing a PMHS, nor helpline providers strictly adhering to all of the national standards for operating a PMHS. However, the findings do suggest that PMHS provide value to patients and carers at a time when they are feeling particularly vulnerable. Additionally, the findings also highlight that, currently, the NHS does not provide an adequate nor efficient support system for patients and carers who wish to seek information regarding their medicines during the transition from secondary to primary care.

9.3 Findings in relation to the wider research context

The following sections briefly describe how each of the five elements of RE-AIM were examined throughout the five studies comprising this research, summarises the findings that were generated, and compares the findings to relevant literature. The five elements of RE-AIM have been re-ordered here so that ‘AIM’ precedes ‘RE’, since the existence and delivery of an intervention precedes its usage and effectiveness.

9.3.1 Adoption

The adoption of PMHS was examined in Studies 1 and 4 only, because these two studies explored the provision of PMHS from the perspectives of pharmacy professionals, who are ideally placed to have an opinion on why their PMHS was adopted, or why they have not adopted a PMHS.

A common theme across Studies 1 and 4 is that one of the biggest challenges to adopting a PMHS is inadequate funding and resources. Lack of resources/ funding was the main reason why almost half of NHS Trusts did not provide a PMHS, suggesting that this is an important barrier to providing this service. *Resources* was also one of two themes that were generated from the analysis from interviews with pharmacy professionals regarding their PMHS. In line with the findings from Study 1, many participants described the lack of specific funding and resources for their PMHS, and how their service was set up as an additional role for the hospital pharmacy team regardless. Lack of resources and staffing have also been found to be reasons for limited adoption of other pharmacy services, such as optional 'enhanced' services within community pharmacies (2-7).

The survey study (Study 1) also found that there was disparity of adoption of PMHS within England, since this varied according to type of Trust and region. This shows that there is inequity in the provision of medicines-related support following hospital discharge, with patients of mental health and community services being at a disadvantage compared to patients of acute and specialist services. This accords with a growing body of research showing that there are inequalities in healthcare provision for individuals with mental illness (8, 9). Additionally, the proportions of Trusts in the North and Midlands of England that provided a PMHS was typically lower than the proportions of Trusts in the southern regions of England. These findings also highlight how the lack of adoption of this service affects its reach (i.e., it is not reaching those patients and carers who may need help, from the Trust types and regions where a PMHS does not exist).

9.3.2 Implementation

The implementation of PMHS was examined in Studies 1, 4 and 5, primarily focusing upon the access, availability, and promotion of PMHS. In the survey study exploring how PMHS are operated in England (Study 1) the implementation of

PMHS was examined by comparing how current practice meets with national standards for operating PMHS. Adherence to the standards could be improved regarding all three aspects of providing a PMHS (compliance with all standards pertaining to PMHS availability, access, and promotion, was 5%, 15%, and 2%, respectively). In the qualitative studies of pharmacy professionals' experiences and perceptions of providing a PMHS, and service users' experiences of contacting a PMHS (Studies 4 and 5, respectively), participants in both studies perceived that the availability, access, and promotion of PMHS could be improved. The findings from Studies 4 and 5 therefore correspond with the findings from Study 1.

9.3.2.1 Availability of patient medicines helpline services

Studies 1 and 4 show that the availability of PMHS could be improved, since only about half of PMHS are available throughout the day during typical working hours, and very few Trusts provide their PMHS out-of-hours (i.e., evenings and weekends). Pharmacy professionals also described how a consequence of limited funding/resources is that the availability of PMHS may be inadequate. In Study 5, service users expressed how PMHS could be improved with staffing beyond typical working week hours, with some feeling concerned about needing the service when it was unavailable. This highlights that PMHS may not always be considered a timely source of support, since the service is not available all the time.

Little research has explored service users' preferences regarding the availability of pharmacy services. However, the research that has been conducted accords with the findings from this doctoral research. For example, two studies have examined the importance of availability of community pharmacy services (10). The first was a survey study by Krska et al., published in 2010, which examined the views of three hundred members of the general public on the role of community pharmacies in public health (11). One of the main facilitators to using community pharmacies was their long opening hours. However, a limitation of this study is that respondents were recruited from one city within one region of England, and so the findings may not be representative of the general population. Similarly, only one mode of data collection was used (face-to-face, with questions asked verbally), which may have resulted in biased responses. The second study was a large survey conducted by Saramunee et al., and published in 2016 (n = 2,661) (12). Overcoming the limitations of the study by Krska et al., data were collected using three modes (participants had the option of completing the survey face-to-face, by

telephone, or by post), and recruitment was conducted within fifteen regions of England. Saramunee et al. found that the majority of respondents reported preferring community pharmacies to be open on a Saturday (approximately 65%), with about half of respondents wanting community pharmacies to be open on a Sunday (approximately 46%). Additionally, over half of respondents endorsed community pharmacies being available in the evening, particularly amongst those working full-time. A limitation of this study is that response rates for the three modes of data collection were low (approximately 20%), which may have resulted in biased responses (response rate for the study by Krska et al. was not reported).

As with PMHS, studies of enhanced community services show that the numbers performed are dependent upon pharmacists' availability (e.g., the working hours available to conduct reviews; available time away from core responsibilities) (4, 6). Studies also suggest that, once adopted, the implementation of healthcare services within the NHS more widely, not just within pharmacy services, can be limited due to inadequate staffing and resources (13-16). The NHS has struggled to meet the rising demand of the health and care needs of the population within the constraints of available resources, particularly during the period of austerity, which has seen a reduction in the average annual NHS budget increase (1.1% per year between 2009/10 and 2020/21, compared to the typical average of 3.7% per year since the NHS was established) (17). Efficiency is therefore an important value in healthcare provision, where limited resources need to be used carefully and thoughtfully in order to maximise positive outcomes with what is available.

9.3.2.2 Access of patient medicines helpline services

The findings of Study 5, which explored service users' experiences of using PMHS, show that patients and carers value easy access to medicines information, and that contacting a PMHS results in quicker access to help than contacting a GP. Ease of access to pharmacy services has been found in other studies. For example, in a systematic review by Hindi et al., (10) community pharmacists were perceived to be more accessible for situations that were considered by service users as not serious enough or worthy enough of GP's time. Additionally, participants in such studies often mentioned easier access in relation to not having to book an appointment to speak to a pharmacy professional, compared to having to see a GP.

Findings from this PhD also suggest one potential way to improve access to PMHS is to provide additional access methods other than the telephone. Options may include email, online chat, or video consulting (VC) (e.g., via Skype or Zoom). The 2019 NHS long-term plan mandates that patients and carers will have access to healthcare services online via VC within the next five years (18). Additionally, the covid-19 pandemic is accelerating the expanded use of VC for providing healthcare services that do not require attending a healthcare setting (19). For this doctoral research, the survey study examining the operation of PMHS in England found that, in 2017, no NHS Trusts were providing their PMHS via VC. Similarly, a recent study that surveyed GP practices in five areas of the UK found that none were providing VC as an access method for patients (20). However, some VC services are now available (21, 22), and studies suggest that there is a demand for VC from patients (23, 24). For example, a recent qualitative interview study by Donaghy et al. explored the acceptability, benefits, and challenges of VC in primary care, between patients and clinicians (24). They found that patients and clinicians considered VC as superior to telephone consultations regarding reassurance, building rapport, and communication, as a result of having visual cues. VC was also considered potentially useful as time-saving alternatives to face-to-face consultations. However, technical issues were common, and the technical infrastructure required to allow VC to become routine was considered a significant barrier. The latter may no longer be an issue, though, because the covid-19 pandemic is accelerating the expanded use of VC for providing healthcare services that do not require attending a healthcare setting (19).

Relatedly, Hammersley et al. conducted a non-randomised, quasi-experimental study to compare the content, quality, and experience of VC, telephone, face-to-face consultations with NHS GPs (25). The study found that both VC and telephone consultations were comparable in terms of content and quality. This suggests that VC may also be a useful access method for PMHS. Participants chose the access method they preferred, with younger patients typically opting for VC. Similarly, a study by Johnston et al. found that, out of a survey of 270 patients in Scotland, patients under 60 years of age were over two-times more likely to use VC, if it were available (23). These findings are important regarding the use of PMHS. The qualitative study of service users' experiences of PMHS (Study 5) suggested that enquirers would prefer to access the service via telephone, but that other options (e.g., email, apps, and VC) might be more appealing to younger individuals. However, this finding may be unsurprising, given that the average age

of participants in this study was 68 years, and that all participants in this study were chosen to be participants because they opted to contact a PMHS (i.e., a telephone helpline). Therefore, it may be possible that the sample selection process filtered out individuals who would prefer to contact the service via other methods.

To date, no high quality studies, such as randomised controlled trials, have been conducted that examine patients use of, and preferences for, accessing NHS advice services by telephone versus online. This is surprising, since NHS 111 is now available online (26), and two NHS apps have been developed; one for patients to book appointments to see a GP (27), and another for patients to access a virtual assistant to check minor symptoms and to offer basic advice (28). However, a study by Eminovic et al., published in 2004, examined 25 patients' experiences and views of using a pilot web chat for NHS Direct (29). They found that web chat sessions lasted on average 30 minutes, which was twice as long as the average telephone call to NHS Direct. Additionally, participants provided their views regarding the use of the web chat version, suggesting that it was beneficial to be have information written down so that it could be re-read, and that access to NHS Direct via web chat is easier than by telephone.

9.3.2.3 Promotion of patient medicines helpline services

Across studies 1, 4 and 5, the promotion of PMHS was found to be minimal. For example, PMHS are typically not promoted at all of a Trust's hospital sites, and pharmacy professionals described that their service is not sufficiently promoted, often as a result of lack of time and resources. Service users also reported that PMHS could be improved by increasing patients' and carers' awareness of the service via improved promotion. Pharmacy professionals also commented upon the link between the lack of promotion of their service, and its perceived underuse. Promotion of PMHS is important because if patients do not know that the service exists, they cannot use it, thus the opportunity to resolve medicines-related issues is missed. This may result in harm to patients (30). This highlights the link between the implementation of PMHS, and their reach. These findings accord with related literature, which suggest that there has been low public awareness, promotion, and uptake of extended community pharmacy services in the UK, such as Medicines Use Reviews (a review of a patients' medicines following hospital discharge; (31)), New Medicines Services (support to help patients be adherent to new medicines for certain high-risk conditions; (32)), and public health services (e.g., stop smoking) (5,

10, 33-45). Studies also show that community pharmacists who provide enhanced pharmacy services are aware that patients lack awareness of such services, and that they are under-promoted (5, 46-48).

Despite a large body of research showing low levels of public awareness of services that community pharmacies offer, very little research has been conducted to explore the best promotional techniques for increasing the uptake of pharmacy services. A large survey study conducted by Saramunee et al., and published in 2016, identified the promotional methods for pharmacy public health services that the general public consider as likely to influence them (12). From 2,661 responses, 89.4% of participants endorsed promotion of pharmacy services via personal recommendation from a health professional. Other highly endorsed preferences were posters in GP surgeries (76.7%) or in pharmacies (71.0%). The findings by Saramunee et al. accords with the findings from this doctoral research. Service users also expressed a preference for being told by healthcare professionals about the availability of the Trust's PMHS. However, this research also found that one of the least used promotional methods by pharmacy teams to promote their PMHS was having staff routinely tell patients about their PMHS. The most widely used promotional method was providing patients with leaflets or business cards about the service. However, business cards and leaflets may not be seen, which will affect the service's reach.

9.3.3 Maintenance

The maintenance of PMHS was examined in Studies 1 and 4. The findings suggested that, once adopted, PMHS are likely to become a relatively stable service for NHS Trusts. At the time of data collection in 2017, on average NHS Trusts had been operating for six years, with the longest service running for twenty-four years. Interviews with pharmacy professionals provided insight as to why PMHS are maintained. Findings highlighted the importance of ensuring that PMHS are embedded within NHS Trusts. For example, it is important that other staff know about the helpline and see its benefits, so that they value it as a source of support (e.g., it frees up their time by directing patients to it). This accords with literature pertaining to UK pharmacy services, which acknowledge the importance of other healthcare professionals knowing what pharmacists and their services can offer (5, 6, 49-52). Additionally, in this doctoral research, pharmacy professionals reported that being able to help people by providing a PMHS gave them high job satisfaction,

which may also be another reason for maintaining it. Studies suggest that providing a helping and/or caring role can contribute to job satisfaction (53). However, roles with increased workload and limited patient interaction can contribute to pharmacy professionals experiencing job-related stress and decreased job satisfaction (54). In this doctoral research, pharmacy professionals also perceived several benefits to providing a PMHS, such as preventing patient harm, and correcting medicines-related errors. Such perceived benefits may also be a motivator for maintaining a service that is not funded. Motivators for providing a PMHS, such as job satisfaction, perceived positive outcomes, and embedding the service within the wider organisation, accord with theoretical explanations for the maintenance of behaviour (55). For example, a systematic review of behaviour theories suggests that behavioural maintenance motives include enjoyment of behaviour and satisfaction with outcomes, and that the maintenance of behaviours is facilitated if there is an alignment between the behaviour (i.e., providing a PMHS) and one's environment (i.e., support of the wider organisation) (55).

Some Trusts reported previously operating a helpline that had been discontinued. The main reason for closure was a lack of resources/funding, which, as established above, was the main reason why Trusts do not adopt this service in the first place. Relatedly, some pharmacy professionals described the difficulty in obtaining funding due to the low number of enquiries received by the service. This suggests a difficult situation where the numbers of enquiries are too small to justify additional funding/resources, yet without additional funding/resources, the number of callers is unlikely to increase (i.e., not enough resources to promote the service and provide for the increased workload). Therefore, many PMHS may be unable to move beyond being suboptimal services.

9.3.4 Reach

The findings from Studies 1, 3, and 4 suggest that the reach of PMHS could be improved. The median number of PMHS enquiries per Trust was just five per week, which accords with findings from previous studies (56-58). Five enquiries per week is less than might be expected when considering the number of discharges that occur at NHS Trusts (59), and that approximately 44% of individuals may experience medicines-related problems following discharge (60, 61). Relatedly, pharmacy professionals in the qualitative study (Study 4) also described that they perceived their service as being underused. Reasons for not reaching patients

include under-promotion of the service, and lack of availability of the service (including not being available out-of-hours).

The reach of PMHS was explored further, whereby the characteristics of PMHS enquirers was examined through a systematic review of nineteen studies. Comparing PMHS enquiry data to Hospital Episode Statistics (HES) data, the findings showed that users of PMHS are broadly representative of hospital patients regarding gender, but not age. The age difference may suggest that PMHS are particularly valued as a source of support by people who are at heightened risk with their medicines, since there is an association between age and polypharmacy (62).

The findings also showed that there is variability across Trusts as to who can use PMHS (e.g., not all Trusts allow outpatients or carers to use the service), which is another factor that will affect the reach of PMHS. Relatedly, some Trusts provide their PMHS to members of the public as well as patients and carers of their own Trust. Given that the promotion of PMHS to patients at NHS Trusts in England is often limited, and helplines are typically under-funded and under-resourced, it may be premature to also make the service available to members of the public. Members of the public have the options of seeking medicines-related support from other sources, such as NHS 111 and community pharmacies. However, this highlights that the public more widely also have a need to seek support regarding their medicines, and that consideration is needed as to how best to support everyone, not just patients transferring from secondary to primary care.

9.3.5 Effectiveness

The effectiveness of PMHS was examined in Studies 1, 2, 4, and 5. However, these studies all explore perceived benefits rather than hard outcomes (e.g., readmissions, symptoms, disease recurrence). This is because two of the studies were qualitative, and one of the other studies relied upon existing data (systematic review), which primarily comprised service user satisfaction survey data. These studies were designed and conducted for this doctorate since, at the start of the doctorate, there was a lack of high-quality research on this topic. Additionally, these studies have provided the foundations for further research. For example, this doctoral research has provided evidence of the lack of studies exploring *actual* benefits of PMHS, rather than *perceived* benefits of PMHS.

Across the PhD studies, the main perceived benefits of PMHS were avoiding or preventing harm to patients, improving patient medication adherence, providing patients with reassurance, helping to optimise patients' medicines, supporting patients' discharge, reducing the burden upon other healthcare services (e.g., primary care), and providing a mechanism for fixing issues before the result in formal complaints to the Trust. The findings from interviews with service users corroborated these findings, and added more depth. The findings illustrate how PMHS provide support during the uncertain transition of care period from hospital to home, when patients and carers often feel vulnerable because support is less available. Participants described how PMHS met their need for timely and easily accessible support, and quick resolution of their issues. PMHS were perceived as best-placed to answer enquiries that arose from hospital care. Participants described feeling reassured from speaking to pharmacy professionals.

A precursor to NHS hospital pharmacy services providing MI to patients was hospital pharmacy services providing MI to healthcare professionals. The aim of this was to provide evidence-based information to hospital staff who experience barriers to searching and appraising the information themselves (e.g., lacking time, and lacking expertise in accessing, searching, and appraising resources and evidence). Findings from a systematic review of the clinical and economic impact of MI services for healthcare professionals, published in 2002, and a recently published literature review (63, 64) show that studies have also typically explored enquirer opinions of the service. Therefore, similar to the findings of this PhD, the evidence regarding the effectiveness of MI services for healthcare professionals is from subjective data rather than objective data. Hands et al. conclude their systematic review by noting that there is a lack of evidence that MI services for healthcare professionals influence patient outcomes (63). This is pertinent, since the same conclusion can be drawn regarding PMHS from the findings of this doctoral research.

The findings from a recently published qualitative metasummary by Lilleheie et al. show that many patients describe the discharge process as an anxious time, partly because there is uncertainty as to what to expect following their discharge (65). A key finding from this doctoral research was that one of the functions of PMHS is to provide reassurance to patients at a time when they are feeling vulnerable and anxious. This was seen in both the qualitative study of pharmacy professionals' perceptions of providing a PMHS (Study 4) and service users'

experiences of using PMHS (Study 5). Additionally, the systematic review examining the effectiveness of MI services for patients and the general public (Study 2) found that, on average, 65% of service users reported feeling reassured as a consequence of using a PMHS. Delivering reassurance is considered to be a core skill for healthcare professionals (66-68). Providing reassurance has the potential to improve health outcomes, and there is a wealth of literature showing that the impact of reassurance on outcomes is particularly demonstrable in individuals with conditions that are defined by subjective symptoms, such as chronic pain and irritable bowel syndrome (68-70). Reassurance may therefore be impactful when there is uncertainty. This is relevant regarding the effectiveness of PMHS, since patients and carers are contacting the service because they are uncertain about an aspect of their medicines and are seeking clarification from an expert.

The findings from Study 5, service users' experiences of using a PMHS, suggest that one of the reasons why PMHS result in service users feeling reassured is because of the professionalism and characteristics of pharmacy professionals who provide the service. Studies show that such characteristics are appreciated from pharmacy services more widely. For example, when visiting community pharmacies, service users report the importance of characteristics such as friendliness, approachability, knowledgeability, being non-judgmental, ability to build rapport, and possessing good communication skills (5, 11, 38, 40, 41, 46, 71-74). Studies also suggest that service users feel comfortable having discussions with pharmacy professionals (72, 75, 76), and that they may feel more comfortable discussing issues with pharmacy professionals compared to other healthcare professionals (e.g., their GP) (77, 78).

The systematic review of the effectiveness of PMHS also reviewed studies that analysed the types of enquiries received to PMHS. The findings showed that PMHS may also be effective for correcting medicines-related errors and for potentially avoiding medicines-related harm. Medication errors can have significant health and economic consequences, such as adverse drug reactions, reduced medication efficacy, increased use of healthcare services, and death (79). Learning from medicines-related errors in order to implement methods for their reduction is a current NHS and worldwide healthcare priority (79). The national standards for operating a PMHS include having a mechanism in place to feed back to the Trust any medication problems and 'systems errors' identified by patients/carers in order to prevent recurrence (80). However, it is currently unknown how many hospital

pharmacies that provide a PMHS adhere to this standard, and whether there are specific barriers preventing this from happening.

9.4 How should patients and carers receive support with medicines during the transition from secondary to primary care?

One of the main benefits of using a PMHS as perceived by both pharmacy professionals who provide PMHS, and service users who use them (Studies 4 and 5 of this doctoral research), is that PMHS are based at hospitals where the patient received care, and so access to relevant resources to deal with the enquiry are readily available. A recent study by Badiani et al found that, out of 200 enquiries to their PMHS, 75% of enquiries required access to local knowledge in order to address the issue (e.g., access to medical records and healthcare professionals involved in the patient's care) (81). Badiani et al. conclude that their findings support the value of having a network of local PMHS, rather than a small number of centralised services.

Relatedly, in two systematic reviews by Hindi et al., community pharmacists' lack of access to medical records was perceived by the public and healthcare professionals as a significant barrier to community pharmacists' extended roles in the wider health-care system (5, 10). Pharmacy professionals also view the transfer of information between hospital pharmacy and community pharmacy as poor (82). Additionally, patients and the public view community pharmacists' lack of access to relevant health-care providers as another potential barrier to community pharmacists being able to help them (10). These findings, along with the findings of this doctoral research, suggest that PMHS are best-placed within NHS Trusts where patients' received care, rather than provided by other potential sources of support, such as community pharmacies. However, this may no longer be the case if community pharmacies also had access to the relevant resources required to address service users' MI queries. Many community pharmacies do now have access to patients' Summary Care Record, which provides them with the patients' list of GP medications (83). However, this list will not include hospital discharge medications until it has been updated by the patients' GP. Therefore, there could be a delay for patients seeking support from community pharmacists pertaining to medications prescribed from hospital.

In the UK, extending the role of community pharmacists beyond traditional dispensing and supply is valued as an opportunity to demonstrate the worth of the profession, and to further develop the skills of community pharmacists (84). The Royal Pharmaceutical Society's guidance on discharge and transfer planning recommends that community pharmacists, as well as general practitioners and patients, are informed about patients' medicines following hospital discharge, in order to prevent adverse events and to reduce readmissions (85, 86). These guidelines highlight the potential of technology to improve transfer of medicines-related information between hospital and community pharmacies.

The new community pharmacist contract for England has outlined plans for an essential medicines reconciliation service, the *NHS Discharge Medicines Service*, to come into effect from July 2020 (87, 88). This builds upon the Transfers of Care around Medicines (TCAM) services that some NHS Trusts have been providing since 2014 (89). TCAM enables NHS Trusts to send referrals to nominated community pharmacies regarding patients that need additional support with their medicines after leaving hospital. Along with the referral is the ability to access the relevant patient's discharge documentation and records. The community pharmacy is then able to accept or reject the referral, and if accepted, will contact the patient for a post-discharge support consultation. Two main platforms used for TCAM are PharmOutcomes and Refer-to-Pharmacy, and studies have been conducted to evidence their benefits (89-92). NHS England has commissioned Academic Health Science Networks (AHSNs) to roll out TCAMs to 50% of acute Trusts in England by the end of 2020 (89, 93). An evaluation of one TCAM, published in 2020, found that patients followed up by a community pharmacist after being discharged from hospital were significantly less likely to be readmitted to hospital within thirty days (94). However, this was not a randomised controlled trial; it was an observational study comparing referred patients who were accepted for intervention compared to referred patients who were not accepted for intervention. Therefore, the groups were not even matched. This study design is typical of the available evidence pertaining to the TCAM scheme (90, 91, 95), and so, higher quality research is needed to establish the effectiveness of this scheme for reducing readmissions (i.e., a randomised controlled trial). Based upon the limited available evidence to date, the AHSN has estimated that TCAM saved the health economy more than 50 million pounds in 2018-2019 by reducing the number of hospital readmissions (89).

Since NHS England is aiming to eventually roll out the TCAM scheme to all acute Trusts (89), the transfer of patients' admission and discharge information to community pharmacies could mean that community pharmacists may then be in a position to obtain the information required to answer medicines-related questions from patients and carers following their discharge from secondary care. However, this would require *all* hospital patients' admission and discharge information being available to a nominated community pharmacy, and not just those deemed to be high-risk. Therefore, the TCAM scheme would need to be extended to be applicable to *all* patients. An advantage of providing PMHS is that they are available for patients regardless as to whether they are considered to be high-risk or not. Another advantage of PMHS are that they enable people who are ill to access support from their own homes. It is currently unknown whether the TCAM scheme will include the option of telephone consultations instead of having to travel to a community pharmacy in order to receive support. Additionally, a potential limitation of TCAM is that if hospitals do not provide an adequate out-of-hours discharge system, there is a risk that out-of-hours discharges will not get referred to the scheme. Out-of-hours discharges are also a high-risk for medication errors, meaning that this group of patients may not be referred to a scheme that could be particularly beneficial for addressing such errors.

There is also the potential that, in the future, pharmacy professionals at GP surgeries may also be able to answer MI enquiries from patients following hospital discharge, provided that they also have all of the necessary resources. A collaborative pilot scheme is currently being conducted by NHS England, Health Education England, the Royal College of GPs, the British Medical Association's GP Committee, and the Royal Pharmaceutical Society, to test the role and effectiveness of clinical pharmacists in general practice (96). The main aim of this pilot is to reduce the burden upon GPs by having practice-based pharmacists available to provide medicines-related support to patients. Thus, the improved sharing of discharge information from secondary care to primary and community care could enable patients to have a choice as to who to contact following hospital discharge if they subsequently experience medicines-related problems or would like information regarding their medicines. Providing patients with choice around their care is a priority for the NHS, so that patients can make informed decisions about their healthcare to best meet their needs and preferences (97, 98). An alternative view is that having three systems essentially serving the same purpose within different areas of the NHS is an example of unwarranted duplication of care and a waste of resources (99, 100)

that could be confusing to patients, and that a more efficient solution would be to have one system that is adequately resourced.

It is also unlikely that community and GP practice-based pharmacists will be in a position to take over full responsibility of dealing with patients' and carers' medicines-related issues following patients' hospital discharge. Since TCAM currently only applies to acute Trusts, non-acute Trusts (i.e., mental health, specialist, and community Trusts) may need to provide their own medicines information service to their patients. Also, TCAM will only be useful if hospital pharmacists send patients' information to community pharmacists, and if community pharmacists then have the capacity and relevant MI expertise to respond to this information. Studies pertaining to other enhanced community pharmacy initiatives, such as Medicines Use Reviews and New Medicines Service, suggest that community pharmacy staff view providing such additional services as increasing their workload in an already pressured, time-limited environment (5-7, 48, 50, 74, 101, 102). This suggests that community pharmacies may not have the capacity for providing a PMHS for discharged hospital patients in addition to their other roles. However, the current 5-year Community Pharmacy Contractual Framework has committed just over £2.5 billion to expand the role of community pharmacy, and support the introduction of clinical services such as TCAM (88). This suggests that, in the future, community pharmacy could possibly be better-resourced to support patients regarding their medicines than non-funded PMHS provided by NHS Trusts.

Another potential issue for TCAM services is that not all queries to PMHS provided by community pharmacies are likely to be answerable, even if community pharmacies have access to resources pertaining to patients' care via resources like PharmOutcomes. The Badiani et al. study described above found that, of 200 enquiries received to their PMHS, 34% required contacting a hospital-based healthcare professional involved in the patient's care (81). Therefore, it seems possible that approximately a third of enquiries would need to be transferred back to the hospital pharmacy services team in order to provide support to the enquirer. However, the finding by Badiani et al. is limited, since it comes from just 200 calls to one PMHS, where the evaluation was conducted by the providers of the service. This may have resulted in measurement bias, whereby the providers of the service coded the enquiries in favour of the service remaining local to hospitals, since they have a vested interest in the continuation of the service at the hospital (i.e., it is an aspect of their careers). Additionally, it is unknown how many of the 34% of

enquiries that require consultation with a healthcare professional at the hospital could have been avoided. The doctoral research has shown that up to 39% of enquiries to PLMHS may concern errors. Had the errors not occurred, the enquiries to the PMHS would not have been necessary. Similarly, the qualitative study with pharmacists showed that helplines are perceived to be a safety net to also provide support due to inadequate discharge counselling. Had discharge counselling been adequately provided, a further number of enquiries may have been avoided. Therefore, the study design by Badiani et al. could be repeated, using researchers independent of the service, who not only establish the proportion of enquiries that definitely require support from the local hospital, but also take in to account the ones that could have been avoided. It could be that the number of enquiries definitely requiring support from the hospital where the patient received care is small. In which case, this would be a serious challenge to the argument by Badiani et al. that PMHS should be provided by each hospital within the UK (81). Arguably, there may no longer be a need for hospital-based PMHS, and patients and carers could get support with their medicines via a different route (e.g., their community pharmacist, or NHS 111). If hospital-based resources are required for some enquiries, a collaborative approach could be taken whereby community pharmacies are contacted with enquiries initially, and they are then able to contact the relevant hospital for additional information if required. This could also provide a mechanism for hospitals to conduct improvement projects whereby the content of enquiries are used to improve hospital services, therefore potentially reducing the occurrence of such enquiries in the future (i.e., enquiries concerning an error, inadequate discharge counselling, or inadequate information within the discharge summary).

From the service user perspective, patients and carers would also need to be informed as to who to contact with medicines-related queries following hospital discharge (i.e., hospital pharmacy or a nominated community pharmacy). Patients' perceptions about the role of community pharmacists suggest that there is confusion and lack of awareness over what additional roles are provided by community pharmacists, over and above the typical dispensing and supply of medicines (44, 103). Otherwise, such a service would suffer the same issue as PMHS, whereby their use will be hindered by inadequate promotion.

In summary, although PMHS are often provided sub-optimally, the provision of medicines information and support to patients and carers following patients' hospital discharge by alternative sources such as community pharmacists and GP

practice pharmacists are also likely to be limited. Currently, the pharmacy systems pertaining to secondary care and primary/community care exist largely independently and without reference to one another, and all provide services with limited resources. Thus, rather than having a system of multiple poorly funded ways for patients and carers to obtain medicines-related support following hospital discharge, co-ordinated thinking is needed to explore how best to provide such support. For example, a solution could be to devise one adequately funded approach that can then be widely promoted to patients and carers. This PhD has shown that there are certain characteristics of MI provision that are particularly important, and need to be considered when developing such a system. For example, the service needs to be timely, easy to access, well-informed about all patients' care, and known about to all patients and carers at the point of discharge.

Through conducting this doctoral research, my view is that all NHS Trusts should provide a PMHS (even if it is purely an answerphone service that is checked at least once a day), and that the content of enquiries should be used to improve hospital services where possible (e.g., reducing medicines-related errors, improving discharge counselling, and improving written information given to patients such as discharge documentation). Over time, this should reduce the number of enquiries to PMHS. Little research has been conducted to show that enquiries to PMHS can result in improvements to hospital services. Three studies reported healthcare quality improvement projects using data from their PMHS service. Green (104) and Hall (105) reported projects whereby helpline calls and experiences of service users were used to develop strategies to improve patient safety and discharge. Strategies included providing carers with more medicines information prior to discharge, highlighting problem areas such as errors to staff, and using types of calls received to improve patient information leaflets (e.g., if something is unclear). More recently, Bramley et al. conducted and published the findings of a quality improvement project for improving written information about medicines in patients' discharge letters (56). This involved analysing the data from calls received in one year preceding the change, and reanalysing the calls received in one year after the change had been made. They found that, prior to the change, 24% of calls (n = 98/413) concerned lack of information the discharge letter, and after the change, this decreased to 7% of calls (n = 32/475). However, all three of these studies were conducted by the providers of their own helpline, and further research is needed to establish the improvements that can be made to hospital services as a result of the

content of enquiries to PMHS, and whether such improvements result in a sustained decrease in call volume over time.

9.5 Overall strengths and limitations of this doctoral research

The strengths and limitations of each of the five studies were reported in the studies' discussion sections. Next, the overall strengths and limitations of the doctoral research as a whole are considered.

9.5.1 Overall strengths of the doctoral research

A strength of this doctoral research is that the RE-AIM framework was used throughout the five studies as a uniting framework. With RE-AIM, the emphasis upon the importance of translating research findings into practice accords with the principles of pragmatism, which aims to produce research findings that are useful and have beneficial consequences (106-109). Other frameworks have been developed for the purpose of evaluating healthcare interventions and services, such as the APEASE criteria, and frameworks proposed by Donabedian, Maxwell, and Higginson, to name a few (110-115). However, RE-AIM was chosen since it is the only framework that purports to examine the *impact* of interventions and services. Additionally, the RE-AIM framework was a useful tool for examining PMHS, since all five of the framework's dimensions are relevant for examining this particular service. At the start of this doctorate, noticeable gaps in the literature were regarding the number of Trusts that provide a PMHS, the use of these services, an exploration as to how different Trusts provide their PMHS, and evidence regarding their effectiveness. RE-AIM acknowledges that the examination of the impact of an intervention requires greater understanding than solely focusing upon its effectiveness. RE-AIM also acknowledges that it is useful to examine an intervention by evaluating both the setting (i.e., NHS Trusts and pharmacy professionals who provide the service) and the individual (i.e., patients and carers who use the service). Using the RE-AIM framework has therefore ensured that the evaluation of PMHS has been more comprehensive than solely focusing upon exploring the effectiveness of these services. However, RE-AIM is a detailed framework, with each of the five elements comprising sub-elements that are considered by the framework's developers as important to study when examining the impact of an intervention or service (116). Due to time and resource constraints, it was not possible to study all aspects of the RE-AIM framework in depth (e.g.,

there was not enough time to explore the longer-term impact that the advice may have had upon service users), and this is discussed further in the Limitations section below.

Another strength is that this research used mixed methods, which was important in order to address the overarching research question. Studies adopted either a quantitative or qualitative approach (Study 1 used a mixed approach, albeit weighted towards quantitative). Both quantitative and qualitative approaches have strengths and limitations; they enable different questions to be answered, and produce different types of knowledge (106, 108, 117, 118). In this research, quantitative methods have been useful for providing descriptive data in order to understand how many Trusts provide a PMHS, the different ways that PMHS are provided, and for whom. Additionally, quantitative methods have been useful for evaluating the effectiveness of PMHS, and the types of callers and enquiries, through the collation of quantitative data in the two systematic reviews. Qualitative methods have been useful for exploring pharmacy professionals' and service users' perceptions of providing and using PMHS, respectively. This has added a deeper layer of understanding to the quantitative data (e.g., understanding *why* PMHS were adopted by NHS Trusts, understanding the reasons why service users find PMHS beneficial, and establishing the ways in which PMHS could be improved). Thus, quantitative methods have been useful because of their generalisability of findings, and qualitative methods have been useful for providing depth and meaning. The combination of quantitative and qualitative methods results in what Turner and colleagues describe as complementary strengths and non-overlapping weaknesses, with the product being superior to that of monomethod research (108, 119).

Another strength of this doctoral research is that data collection tools were developed with feedback from members of the public (e.g., individuals who had experienced a hospital discharge recently, or carers of such individuals), or pharmacists with expertise in MI. The National Institute for Health Research and the Health Research Authority define patient and public involvement in research (PPIR) as research that is carried out 'with' or 'by' patients and/or members of the public rather than 'to', 'about' or 'for' them (120, 121). PPIR is important because it results in service users feeling empowerment and valued, and it can offer unique and invaluable insights and expertise, making research more effective and credible (122-125). For this research, information sheets and data collection tools were checked and commented upon by members of the public and pharmacy

professionals, in order to improve their readability and usefulness for collecting meaningful data that answered the studies' research questions. Research suggests that PPIR is often not well reported in research articles (126). For example, Mathie et al. conducted a UK scoping study to establish the proportion of a selection of studies which had evidence of PPIR (126). They found that 51% of studies had some evidence of PPIR, and that the extent of this varied widely. Therefore, for transparency, publications from this doctoral research have clearly stated the extent of PPIR.

Finally, another strength of this doctoral research is the use of checklists and tools to enhance the rigour and transparency of the studies. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were used during the planning, conducting, and reporting of the two systematic reviews (Studies 2 and 3) (127-130). The PRISMA guidelines and checklist were developed by a group of 29 review authors, methodologists, clinicians, medical editors, and consumers, with the aim of improving ways in which authors can ensure the transparent and complete reporting of systematic reviews and meta-analyses. Since Studies 4 and 5 were qualitative, the consolidated criteria for reporting qualitative research (COREQ) and the standards for reporting qualitative research (SRQR) were followed (131, 132), as recommended by the British Medical Journal (133). Designing, conducting, and reporting research studies is a complex process that involves many decisions. Checklists and tools are useful for ensuring that this is done systematically, by highlighting what should be done in order to conduct a study to a high standard, and to be transparent as to where deviations occur. The use of checklists and tools throughout this research have therefore enhanced the transparency regarding the decisions made.

9.5.2 Overall limitations of the doctoral research

With hindsight, a limitation of Study 1 is that the survey did not ask pharmacy professionals how their PMHS is funded (e.g., through an existing budget for medicines information or pharmacy services, or whether there is a specific budget just for the PMHS). This quantitative data would have been useful in relation to the findings from Study 4, in which interviewed pharmacy professionals described having limited resources and staffing to provide their PMHS. Limited resources and staffing was a significant issue, which is why *Resources* was one of the two themes to be generated from the data for Study 4. Knowing the proportion of Trusts that do

not have specific funding for their PMHS would have been a useful addition to this qualitative finding. The only published data regarding the proportion of PMHS that are funded comes from a study Raynor et al., that was published in 2000 (i.e., that 85% of 66 PMHS are funded through an existing budget).

Also with hindsight, Study 5 could have been improved had a mixed methods approach been applied (108). In order to obtain the necessary Health Research Authority approvals in a timely way, Study 5 was designed before completing the systematic review examining the effectiveness of medicines information services for patients and the general public (Study 2). A recommendation for future research from this systematic review was that large, multi-site service user satisfaction surveys are needed, since the data primarily came from small, single-site service evaluation studies. Had this been known prior to designing Study 5, an arguably more useful design would have employed a mixed methods approach, in order to make better use of having recruited seven NHS trusts to act as participant identification sites. A PMHS satisfaction survey could have been posted to consenting PMHS users from the seven sites, with a subset of participants selected for further exploration of their experiences using the qualitative methods used in Study 5. This design would have filled an important knowledge gap, and would not have involved significant extra research time, given that the seven sites were already participating in the study. The mixing of nomothetic and idiographic approaches within a single study may have resulted in the generation of additional recommendations for improving the provision of PMHS than are reported in Study 5. Additionally, this design may have overcome a limitation of Study 5 in which PMHS providers acted as gatekeepers to participants, which likely biased the results (i.e., selection bias). For example, they had the option to not advertise the study to enquirers who may have experienced the service negatively. In the alternate mixed-methods design, enquirers would tick a box at the end of the survey, and include their contact details, if they were interested in potentially taking part in an interview to describe their experiences in more depth. This may have resulted in a broader picture of the experiences of individuals who use PMHS. However, selection bias may have still occurred to some extent for the mixed-methods design, given that providers of PMHS would still be required to post surveys to enquirers in the first place.

A third limitation is that not all aspects of the RE-AIM framework were examined via this doctoral research. RE-AIM comprises five elements that are

considered relevant for examining the impact of interventions and services (*Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance*). Each of these five elements comprises sub-elements. For example, *Maintenance* can be explored by examining the maintenance of the intervention/service over time, and also the longer-term impact that the intervention/service had upon the user. The former was examined in this doctoral research (Study 1 and Study 4), yet the latter was not. For this doctoral research, *Implementation* primarily focused upon comparing current practice to national standards. However, other aspects of *Implementation* not evaluated during this research were the consistency of delivery of PMHS as intended, the time and cost of the intervention, and adaptations made to the intervention. Similarly, the reach of PMHS could have been more thoroughly examined in this doctoral research. According to the developers of the RE-AIM framework, aspects of *Reach* include the percentage and representativeness of individuals who are willing to participate in a given programme (134). The evaluation of the reach of PMHS throughout this doctoral research has relied upon examining the average number of calls received to PMHS (Study 1), pharmacy professionals' views as to who can use their service and why (Studies 1 and 4), and a systematic review examining the characteristics of enquirers of PMHS, comparing the data to relevant Hospital Episode Statistics data (Study 3). The latter is the only one from this research that therefore examined the reach of PMHS as defined by its developers. The data collected from the other two studies has still been useful, however, as proxy measures for reach (i.e., the low number of enquiries received suggests that the service could be used more, and knowledge regarding who can and cannot use PMHS helps to define what reach actually is).

Relatedly, although the RE-AIM framework has been useful for examining five constructs that are conceptualised as being important for understanding the impact of interventions, there may be other constructs that are also relevant to the impact of interventions. For example, the APEASE criteria for evaluating interventions has some facets that overlap with RE-AIM, although an element of APEASE that does not overtly form part of RE-AIM is *Acceptability* (110). If an intervention is not considered to be acceptable, its use may be negatively affected, which will limit its impact. For APEASE, *Acceptability* refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders. This could be a useful facet to examine in order to consider ways to improve PMHS, and to explore whether relevant stakeholders can think of better ways of supporting patients and carers regarding medicines following hospital discharge. However, the RE-AIM

framework seemed more relevant for the purposes of this research than the APEASE criteria, since there are useful elements pertaining to the evaluation of PMHS that are within RE-AIM but that are not within APEASE (e.g., adoption and reach). Additionally, at the time of choosing a framework for the research, the APEASE criteria was not evidence-based, and only a few studies had used it. This was another reason why RE-AIM was chosen, given that it was developed in 1999 and has been widely used (1, 135). Acceptability was included in this doctoral research to some extent, as an element of effectiveness (i.e., in the systematic review examining the effectiveness of PMHS (Study 2) and the qualitative study of service users' experiences of using a PMHS (Study 5)).

A further limitation is that the doctoral research did not seek to establish whether compliance with the national standards for providing a PMHS results in improved effectiveness, nor whether the effectiveness of PMHS varies across sites irrespective of compliance to the standards. For example, even if all standards are met, the quality of the information provided to patients and carers may vary depending upon the skills and knowledge of the pharmacist they speak to, and the amount of time that pharmacists are able to give to dealing with the enquiry. Such potential variability was not examined within this doctoral research, yet it may have a significant impact upon the effectiveness of PMHS (e.g., whether the advice was understood, whether the advice was followed, and whether following the advice led to improved health and wellbeing).

9.6 Ideas for future research

Out of all the studies that could be conducted, a study examining the cost-effectiveness of PMHS would likely have the most impact in terms of evidencing that PMHS are both needed and worthwhile (136). Therefore, a randomised controlled trial (including an economic evaluation) would be the ideal future project in terms of strength of evidence regarding the effectiveness and cost-effectiveness of PMHS. Since approximately 50% of NHS Trusts do not provide a PMHS, a stepped-wedge design could be appropriate in order to look at the progressive introduction of the helpline to patients at those sites that do not currently provide one (137, 138). A stepped-wedge design is becoming increasingly used to evaluate healthcare services that are already being provided but where the evidence for the effectiveness of the service is limited. It is particularly useful for evaluating interventions that do not rely on individual patient recruitment, since data are

routinely collected. This design could therefore be suitable in this respect for evaluating PMHS. However, conducting such a study is unlikely to be feasible due to the cost of recruiting sufficient Trusts to measure what is likely to be a small effect on hard outcomes (e.g., adherence, symptoms, disease recurrence). Additionally, this PhD research found that, on average, NHS Trusts receive five enquiries to their PMHS per week, and a stepped-wedge design would therefore be unlikely to see an effect, if any exist. However, the number of enquiries per week may increase above five, if the promotion of the PMHS within the trial is increased beyond that of extant PMHS within the NHS. For example, the range of enquiries received to PMHS, as established in Study 1, was 0-50 per week. Therefore, some Trusts received on average 50 enquiries per week. Exploratory analysis showed that number of promotional methods and number of hours of availability were both significantly correlated with number of calls received, suggesting that increasing the number of calls may be possible if improvements to helpline availability and promotion are made.

Based upon the findings from the five studies conducted for this doctorate, and given that most prior studies have been service evaluations whereby providers of PMHS have conducted small-scale studies regarding their own service, there are many potential avenues for future research pertaining to PMHS. However, there are two in particular that would likely have the most impact regarding the provision of medicines-related support following hospital discharge.

9.6.1 Future research study 1

A more thorough approach for understanding the reach of PMHS would be to follow up a cohort of discharged patients from several Trusts that provide a PMHS, in order to explore those patients who subsequently require medicines information, and to compare the percentages and characteristics of PMHS users with patients who choose alternative sources of support. This study design could also provide an opportunity to explore patients' reasons for not seeking MI via the Trusts' PMHS, which would be useful for establishing further recommendations for improving the use of PMHS (i.e., to make the prospect of using them more appealing to such patients). This study could seek to address the research questions in Box 1.

Box 1. Research questions for a hypothetical study to examine the reach of PMHS, and medicines information needs following hospital discharge

1. What percentage of patients experience medicines-related issues in the month following hospital discharge?
2. What types of medicines-related issues do patients experience following hospital discharge?
3. What do recently discharged patients do in order to meet their medicines-related needs?
4. What percentage of recently discharged patients are aware that their hospital operates a patient medicines helpline?
5. What are recently discharged patients' reason/s for choosing their source of medicines information and support?
6. What are the barriers to seeking medicines information and support via an NHS Trust's patient medicines helpline?

Potential participants could be asked to complete a survey approximately four weeks after they have been discharged from hospital. Four weeks would be appropriate, since previous literature suggests that medicines-related problems following hospital discharge are typically disclosed within this timeframe (60, 61). At the end of the survey, participants could provide their contact details if they would be willing to partake in a semi-structured interview to explore their experiences in more depth. This latter part of the design would be particularly useful to answer research questions 5 and 6 in Box 1.

The survey part of the study could include the Satisfaction with Information about Medicines Scale (SIMS) (139), to assess patients' satisfaction with the overall information they received about their medicines during discharge from hospital. The SIMS has had its psychometric properties assessed, showing satisfactory reliability and validity in patients from eight diagnostic categories (total n = 826) (139). The

SIMS was not used in this doctoral research, since enquiries to PMHS typically pertain to one aspect of medication (e.g., administration, dosage, side effects, interactions), and the SIMS explores satisfaction with MI more broadly, such as MI received during hospital admission (140, 141). Therefore, the SIMS was not considered suitable for exploring the satisfaction of using a PMHS, since it was likely that only one of its seventeen items would have been relevant to each participant who used a PMHS. However, for this future research study, the inclusion of a relevant and psychometrically robust tool such as the SIMS would be advantageous for establishing gaps regarding people's satisfaction with their medicines, and to help answer a broader question as to what information about medicines patients and carers actually need after discharge from hospital. The SIMS has been used for establishing what medicines information patients want (e.g., (142)), with findings from studies (those that used the SIMS and those that did not) suggesting that side effects, interactions, and duration of treatments are common information gaps (142-144). Establishing the needs that patients have regarding their medicines in a large, multi-site cohort study would be novel and informative for developing recommendations for providing services that can cater to their needs.

This study design would therefore not only be useful to explore the reach of PMHS, but also to add to the evidence-base regarding the lack of MI provided during admission to hospital, and the need for MI support following hospital discharge. Regarding the latter, research suggests that between 36% and 44% of patients discharged from hospital within the UK will experience medicines-related problems (60, 61). However, this finding comes from two studies which had small sample sizes (n = 27, n = 96) (60, 61), and where one of the studies was conducted at just one NHS Trust, thereby limiting the generalisability of the findings (61).

This study design would also be useful for examining patients MI needs and MI-seeking behaviours more broadly, rather than solely focusing upon individuals who use PMHS (e.g., calculating the percentages who seek medicines-related support via other sources such as GPs, community pharmacists, NHS 111, A&E). Broadening the scope would highlight how much of an impact medicines-related problems following hospital discharge have upon other services, such as primary care. Thus, examining what patients do regarding medicines-related problems following hospital discharge, and why, could result in strategies to improve patient support (e.g., improved and increased sharing of discharge information between

pharmacy teams in secondary and primary care) which may help to reduce the demand on other healthcare services such as GPs and A&E, and reduce avoidable medicines-related readmissions. The study could also be useful for exploring potential differences in MI needs between service users of different Trust types. For example, service users of acute Trusts and of mental health Trusts may seek or desire support from different services, based upon their perceptions as to what services are available to them. Capturing such depth of information is why a mixed-methods study design, with a qualitative semi-structured interview element, would be advantageous.

9.6.2 Future research study 2

Since NHS England has commissioned Academic Health Science Networks (AHSNs) to roll out Transfer of Care Around Medicines (TCAM) services to 50% of acute Trusts in England by the end of 2020 (89, 93), it may be possible for community pharmacists to answer MI queries from patients following their discharge from secondary care. However, as described above, having multiple yet poorly funded MI services may not be an efficient solution to the problem of supporting patients and carers with their medicines following hospital discharge. Currently, only half of Trusts provide a PMHS, not all Trusts yet provide the TCAM service, and not all GP practices employ a practice-based pharmacist. Moving forward, an important aim would be to consider and establish a system that is adequately resourced, efficient, and utilised, where patients know who to go to for MI support, and where whoever is dealing with the enquiry has all of the information to provide timely help.

Another useful research avenue would therefore be to explore the views of relevant stakeholders (e.g., pharmacy professionals, service users, service commissioners) regarding how best to provide medicines-related support to patients and carers following hospital discharge. For example, focus groups could be conducted with hospital MI pharmacists, community pharmacists, chief pharmacists, GPs and general practice-based pharmacists, service users, and service commissioners, to establish their views regarding the future of PMHS, and also community pharmacists being a source of medicines-related support to patients following discharge from secondary care. Regarding the latter, such research could also explore the barriers and facilitators to achieving this, and seek the views of service users regarding the sources of support that they actually want, and the reasons for this. Similar to Future Research Study 1, yet using focus groups instead

of survey methods, this could also provide another opportunity to establish patients' needs regarding medicines information after being discharged from hospital, and a discussion with relevant stakeholders as to whether PMHS are currently able to provide such information. Ideally, each focus group with pharmacists would comprise an equal number of stakeholders. Additionally, each pharmacist type could be broken down further, to include hospital MI pharmacists from different NHS Trust types (e.g., acute, mental health, specialist), and to include community pharmacists from independent and branch pharmacies, in both rural and urban areas. Similarly, focus groups with service users could include a range of demographic and background characteristics (e.g., different genders and ages, and include both patients and carers), and service users from different NHS Trust types (e.g., acute, mental health, specialist) and different geographical areas (e.g., rural, urban). This would ensure that a wide range of views are captured, which is important for ensuring that services are developed to meet people's needs.

9.7 Recommendations for practice

9.7.1 A system for supporting *all* patients with their medicines

The findings from this research show that PMHS are valued, and have a number of perceived benefits for service users and healthcare organisations. Healthcare organisations that currently do not provide an MI service to patients should consider whether the evidence is sufficient to merit developing their own PMHS. However, the findings from this doctoral research also suggest that recommendations must be achievable within a resource-limited context. Therefore, it may not be possible for sites that do not currently provide a PMHS to do so. Nevertheless, in terms of equity, patients and carers of Trusts that do not provide a PMHS may be less able to receive timely and expert help with their medicines following their discharge, which could possibly result in them suffering as a consequence. Additionally, the same applies to Trusts that *do* provide a PMHS, but which has limited availability and/or is poorly promoted. Ideally, what is needed is a service, or co-ordinated system of services, that are available for *all* patients whenever they need help, so that anyone can easily access expert support with their medicines. Budget holders/commissioners and senior management within the NHS should consider how best to support patients after discharge, and whether this should involve funding PMHS provided by NHS Trusts. Additional research is likely

to be needed to establish the best way to achieve this, as described in section 9.6, above.

9.7.2 Improving existing patient medicines helpline services

Since the focus of this doctoral research is upon PMHS, the following recommendations are for those NHS Trusts that currently provide this service. It seems likely from the findings of this doctoral research that existing PMHS are underused (e.g., on average NHS Trusts receive five enquiries per week, and pharmacy professionals who provide PMHS perceive them to be underused). In order to increase the impact of PMHS, helpline providers are encouraged to consider ways to increase their use. The findings from this doctoral research suggest that this may be achievable by improving the access, availability, and promotion of PMHS. Examples of this are presented in Box 2.

Box 2. Examples of ways to improve the access, availability, and promotion of patient medicines helpline services (PMHS)

- Increase the number of promotional methods, and/or conduct local improvement projects to establish the types of promotional methods that patients and carers recommend, and would most likely see and remember.
- Promote the service at all sites within the organisation, and ensure that promotional methods clearly state the purpose of the service, the service's opening times, and types of enquiries that can be made.
- In order to reduce the cost of promotion, and increase the reach of PMHS, helpline providers could promote their service for free by ensuring that their helpline number is included within discharge summaries that patients receive. Some pharmacy professionals in Study 4 described how this particular promotional method resulted in an increased number of enquiries, suggesting that more patients who may need this service will learn of its existence. Additionally, ward pharmacists could tell their patients and patients' carers about the PMHS during ward rounds, informing them that the details of the service will be available in their discharge summaries.
- Extend the hours of availability, such as providing access to the service beyond typical 9–5 working hours (e.g., evenings and weekends).
- Ensure that helpline staff are available to answer the telephone to receive enquiries, rather than relying on answerphones.
- Provide access to the service by other means in addition to the telephone, such as email, webform via the Trust website, online chat, and Skype.

Providers of PMHS are encouraged to use data on types of enquiries to PMHS to produce recommendations for improving local hospital services. For example, in the systematic review examining the characteristics of the types of enquiries received to PMHS (Study 3), six studies reported that enquiries were predominantly about adverse effects, and two studies reported that enquiries were predominantly about antimicrobial drugs. Therefore, potential projects could involve improving patient leaflets and counselling regarding adverse effects and antimicrobial drugs. Additionally, since a proportion of PMHS calls may be avoidable (e.g., calls received as a consequence of inadequate discharge counselling, and/or calls regarding medicines-related errors), PMHS providers could examine the types of calls they receive in order to learn from them and improve practice. Over time, certain enquiries (e.g., those regarding errors) may be reduced, which may also reduce the burden upon PMHS providers. This may result in fewer resources being needed to provide a PMHS. It would also be useful if sites that provide a PMHS were more easily able to share learning from their local projects, and their ideas for implementing and maintaining a PMHS within a resource-limited context. This could be co-ordinated by regional MI centres, and published via the UK Medicines Information network (145).

Providers of PMHS are also encouraged to evaluate the types of enquiries they receive by using standardised categories and coding instructions/training (e.g. those that were developed by the UK Medicines Information network). This will enable the types of enquiries to be more appropriately compared across sites and regions within the UK. Relatedly, the wide variety in error rates found across studies in the systematic review examining the effectiveness of PMHS (i.e. 8–39%; Study 2) may reflect the use of different definitions as to what constitutes a medicines-related error, since the definition of an error has been found to have an effect upon rates (146, 147). We therefore also recommend that sites use a standardised definition of 'medicines-related error', including a standardised categorisation/coding scheme for collecting and analysing enquiry data.

Another recommendation is that PMHS sites conduct service evaluations in order to provide a more detailed and standardised profile of enquirers. In the systematic review examining the types of enquirers to PMHS (Study 3), no studies were found that reported data pertaining to the ethnicity, educational level/socioeconomic status and the average number of medicines consumed by patient enquirers. This would help to establish how enquirers compare to the local patient population, and to enable comparisons across sites. Such data could be useful

to explore whether certain types of patients are less likely to use the service. This could result in projects to understand why, and whether more can be done to provide a PMHS that is equitable and available for *all* hospital patients who require support with their medicines irrespective of their background.

9.8 Conclusions

The aim of this doctoral research was to address the following question: *What is the impact of National Health Service (NHS) patient medicines helpline services upon service users and healthcare organisations?* The findings show that PMHS provide timely medicines-related support to patients and carers following hospital discharge, and that PMHS are perceived as effective and valued from the perspectives of pharmacy professionals who provide them, and patients and carers who use them. However, the examination of the effectiveness of PMHS is limited by primarily consisting of subjective experiences and perceptions (e.g., survey data, a systematic review of service user satisfaction survey data, and two interview studies) rather than hard outcomes (e.g., readmission rates, symptoms and disease recurrence). Additionally, the RE-AIM framework conceptualises that effectiveness alone does not determine a service's impact. The findings from this doctoral research also show that the impact of PMHS is hindered by its limited adoption, implementation, and reach. The limited adoption, implementation and reach of PMHS appear to be a consequence of limited resources and staffing. However, despite this, the findings also suggest that, once adopted, PMHS are likely to become a relatively stable service for NHS Trusts. PMHS are maintained because they are perceived to be beneficial and valued, despite their delivery also being perceived as suboptimal.

Based upon the findings of this doctoral research, recommendations have been made to improve the delivery of PMHS, in order to provide a more valued and efficient service. There will always be limited resources available to provide healthcare services, and this is evident not just from the findings of this doctoral research, but also the examples provided in this discussion regarding pharmacy services and healthcare services more widely. It is therefore important to make the most of the resources that are available, and to use them wisely. Thus, one recommendation is for pharmacy professionals who provide a PMHS to share their learning with the wider MI community regarding ways to provide a PMHS with limited resources. This will enable PMHS providers to learn from each other how

best to provide their service within a resource-limited context. However, since PMHS are currently provided suboptimally in terms of the numbers of Trusts that provide them and the varying ways that they have been implemented, and since research has not been conducted to establish their cost-effectiveness, another recommendation is for stakeholders to consider the best way to support patients with their medicines following discharge from secondary care. One option may be for patients to nominate a local community pharmacy to receive their discharge information so that the community pharmacy can be contacted regarding any queries. However, research is needed to establish whether this would be an improvement upon the current system of support. Therefore, the research recommendations from this doctoral research focus upon exploring the future of PMHS and establishing the best way to support all patients who need help with their medicines following hospital discharge, which is cost-effective without diminishing quality.

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Appendix 1: Survey questions (Study 1)

Survey 1 questions and answer options

Question	Answer type	Answer options (if applicable)
A patient medicines helpline can be defined as: "A telephone line, provided or commissioned by an NHS Trust, to enable patients and/or their carers to contact a pharmacy professional for medicines-related information and advice. It is advertised as being available for this purpose. It is specifically for medicines-related information and advice, and not for general clinical advice." Do patients and/or carers from your NHS Trust have access to a patient medicines helpline, as defined above? *(This can include a helpline which is run by your Trust, or by another provider)*	Multiple choice, single response	Yes No
Questions for Trusts that provide a medicines helpline (either via their own Trust or another Trust)		
Some NHS Trusts provide patients with access to a medicines helpline which is operated from another Trust. Other NHS Trusts may operate one or more patient medicines helpline (e.g., two helplines run from different hospitals within a Trust; or a general medicines helpline for all patients, and a specialist medicines helpline for patients of a particular clinical group). How many patient medicines helplines are being operated at your NHS Trust? *(Please only include helplines which are specifically for patients to access information/advice about medicines only, rather than general clinical advice)*	Multiple choice, single response	0 (Patients and carers from my NHS Trust have access to a helpline that is provided or commissioned by another Trust). 1 2 3 4 5
Questions for Trusts that provide a patient medicines helpline via another organisation		
For whom at your NHS Trust is the patient medicines helpline available? *(Please read all options and tick all that apply)*	Multiple choice, multiple response	Carers of patients from my NHS Trust. Discharged inpatients from my NHS Trust. Outpatients from my NHS Trust.

		Any patient whose medication was prescribed and/or dispensed by my NHS Trust. A specific clinical group of patients at my NHS Trust (If so, please specify in 'Other', below). Other (please specify).
Who provides the patient medicines helpline? *(Please tick all that apply)*	Multiple choice, multiple response	Medicines Information Team/Service at another NHS Trust. Dispensary at another NHS Trust. General Clinical Pharmacy Service at another NHS Trust. Specialist Clinical Pharmacy Service at another NHS Trust (If so, please specify the type of specialist service in 'Other', below). Other (please specify).
From approximately what year was the patient medicines helpline service available to patients from your NHS Trust?	Free text box	
Who is the helpline *promoted* to, at your NHS Trust? *(Please tick all that apply)*	Multiple choice, multiple response	Discharged inpatients. Outpatients. Other (Please specify).
How is the patient medicines helpline promoted to patients at your NHS Trust? *(Please tick all that apply)*	Multiple choice, multiple response	Posters in clinical areas around the Trust. On the Trust website. Leaflet or business card in prescriptions. On medicines labels or medicines bag labels. On patients' discharge summary. Staff routinely tell patients about it (e.g., discharge counselling). Other (please specify).
Where is the patient medicines helpline promoted? Please tick the most relevant statement, below.	Multiple choice, single response	The helpline is promoted at all sites within the Trust. The helpline is promoted at some sites within the Trust. The helpline is promoted at none of the sites within the Trust.

Do the promotional materials for the patient medicines helpline advertise the following? *(Please tick all that apply)*	Multiple choice, multiple response	Days/times of the week that the helpline is available. Examples of types of questions that service users can ask. None of the above.
Are any of these other methods of communication advertised to patients as alternative ways to get in touch for medicines information/advice? *(Please tick all that apply)*	Multiple choice, multiple response	Email. Online web form (e.g., via the Trust website). Face-to-face. Other (please specify).
How were the promotional methods for the patient medicines helpline decided? *(Please tick all that apply)*	Multiple choice, multiple response	Patients from my NHS Trust were consulted. Recommendations from guidelines / published studies. Decided by Pharmacy/MI staff at my Trust. Other (please specify)
Please read the following list and tick the options that you consider to be a major benefit or a minor benefit of providing a patient medicines helpline, based upon your experience. Leave any blank if you do not consider them to be a benefit.	Multiple choice, multiple response	Avoiding harm to patients (e.g., adverse effects, interactions). Identifying errors. Learning from patient experiences. Helping the organisation avoid complaints and possible litigation. Improving patient medication adherence. Supporting patient discharge. Providing assurance that patients can access professional advice at home. Improving the patient experience (e.g., patient satisfaction). Adhering to the NHS Constitution (e.g., patients have a right to information). Reducing visits to other healthcare services (e.g., GPs, A&E). Reducing medicines-related readmissions. Improvement in Trust targets and in national surveys (e.g., Adult Inpatient Survey). Optimising medicines.

Please use the space below if you have suggestions for other benefits of providing a patient medicines helpline which aren't on the list above.	Free text box	
How do you see patient medicines helplines at NHS Trusts developing in the future? (Please consider the future at your Trust, and future changes within the NHS as a whole organisation)	Free text box	
If you have any other comments about patient medicines helplines, or about the answers you have given in this survey, please use the space below.	Free text box	
Questions for Trusts that operate at least one helpline (The majority of questions are asked about each helpline)		
Is there an agreement between your NHS Trust and any other NHS Trusts so that their patients can access the patient medicines helpline being operated at your Trust? If yes, with how many other Trusts is there such an agreement?	Multiple choice, single response	None (There isn't an agreement with any other Trusts). 1 2 3 4 5
For whom is your medicines helpline available? *(Please read all options and tick all that apply)*	Multiple choice, multiple response	Carers of patients from my NHS Trust. Discharged inpatients from my NHS Trust. Outpatients from my NHS Trust. Any patient whose medication was prescribed and/or dispensed by my NHS Trust. A specific clinical group of patients at my NHS Trust (If so, please specify in 'Other', below). Patients from another NHS Trust (e.g., if another Trust shares your Medicines Information Team or Pharmacy Services). Anyone in the local area, regardless of whether they are/were a patient or not. Anyone who gets in touch, regardless of their location. Other (please specify).

Who provides the patient medicines helpline? *(Please tick all that apply)*	Multiple choice, multiple response	Medicines Information Team/Service at my NHS Trust. Dispensary at my NHS Trust. General Clinical Pharmacy Service at my NHS Trust. Specialist Clinical Pharmacy Service at my NHS Trust (If so, please specify the type of specialist service in 'Other', below). Other (please specify).
Approximately what year did the patient medicines helpline first start taking calls?	Free text box	
On average, how many calls to the patient medicines helpline do you receive in a week? *(Please provide an estimate if you are unsure)*	Free text box	
Does the phone line for the patient medicines helpline allow direct dialling from outside?	Multiple choice, single response	Yes No
Is the phone number for the patient medicines helpline a dedicated number, just for the helpline?	Multiple choice, single response	Yes No
What is the charge for calls to the patient medicines helpline?	Multiple choice, single response	Calls are charged at a local rate. Calls are charged at a premium rate. Calls are free.
Who is the helpline *promoted* to, at your NHS Trust? *(Please tick all that apply)*	Multiple choice, multiple response	Discharged inpatients Outpatients Other (Please specify)
How is the patient medicines helpline promoted to patients at your NHS Trust? *(Please tick all that apply)*	Multiple choice, multiple response	Posters in clinical areas around the Trust. On the Trust website. Leaflet or business card in prescriptions. On medicines labels or medicines bag labels. On patients' discharge summary.

		Staff routinely tell patients about it (e.g., discharge counselling). Other (please specify).
Where is the patient medicines helpline promoted? Please tick the most relevant statement, below.	Multiple choice, single response	The helpline is promoted at all sites within the Trust. The helpline is promoted at some sites within the Trust. The helpline is promoted at none of the sites within the Trust.
Do the promotional materials for the patient medicines helpline advertise the following? *(Please tick all that apply)*	Multiple choice, multiple response	Days/times of the week that the helpline is available. Examples of types of questions that service users can ask. None of the above.
Please enter the number of hours per day that the patient medicines helpline is advertised as being available, in the relevant spaces below. Please leave blank any days when the helpline is not available.	Table. Multiple choice, multiple response, with free text box.	Monday Tuesday Wednesday Thursday Friday Saturday Sunday
Is a pharmacy professional always available to answer calls from patients during advertised hours?	Multiple choice, single response	Yes, and there is also an answerphone service where patients can leave a message for out-of-hours calls. Yes. No, although there is an answerphone service where patients can leave a message. No.
Are any of these other methods of communication advertised to patients as alternative ways to get in touch for medicines information/advice? *(Please tick all that apply)*	Multiple choice, multiple response	Email. Online web form (e.g., via the Trust website). Face-to-face. Other (please specify).
How were the promotional methods for the patient medicines helpline decided? *(Please tick all that apply)*	Multiple choice, multiple response	Patients from my NHS Trust were consulted. Recommendations from guidelines / published studies.

		Decided by Pharmacy/MI staff at my Trust. Other (please specify)
Please read the following list and tick the options that you consider to be a major benefit or a minor benefit of providing a patient medicines helpline, based upon your experience. Leave any blank if you do not consider them to be a benefit.	Multiple choice, multiple response	Avoiding harm to patients (e.g., adverse effects, interactions). Identifying errors. Learning from patient experiences. Helping the organisation avoid complaints and possible litigation. Improving patient medication adherence. Supporting patient discharge. Providing assurance that patients can access professional advice at home. Improving the patient experience (e.g., patient satisfaction). Adhering to the NHS Constitution (e.g., patients have a right to information). Reducing visits to other healthcare services (e.g., GPs, A&E). Reducing medicines-related readmissions. Improvement in Trust targets and in national surveys (e.g., Adult Inpatient Survey). Optimising medicines.
Please use the space below if you have suggestions for other benefits of providing a patient medicines helpline which aren't on the list above.	Free text box	
How do you see patient medicines helplines at NHS Trusts developing in the future? (Please consider the future at your Trust, and future changes within the NHS as a whole organisation)	Free text box	
If you have any other comments about patient medicines helplines, or about the answers you have given in this survey, please use the space below.	Free text box	
Questions for Trusts that do not provide a patient medicines helpline (neither via their own Trust, nor outsourced)		

Has your NHS Trust provided patients with access to a medicines helpline in the past?	Multiple choice, single response	Yes No
You answered that your NHS Trust provided patients to a medicines helpline in the past. Please could you provide the reason/s why the patient medicines helpline service was stopped?	Free text box	
Does your NHS Trust have any plans to provide patients with access to a medicines helpline in the future? (i.e., via your Trust, or another provider)	Multiple choice, single response	Yes Possibly No
Research suggests that approximately 50% of Medicines Information Centres in the UK do not operate a patient medicines helpline. We are interested to learn more about the reasons why some NHS Trusts have decided not to operate a helpline. In the space below, we would be grateful if you could please provide the reason/s why your Trust does not currently operate a patient medicines helpline.	Free text box	
If a patient was to contact the Pharmacy Services team at your NHS Trust for medicines information and advice, what would you typically do?	Multiple choice, single response	Answer their query. Advise them to contact another service (e.g., their GP). Other (Please specify).
How do you see patient medicines helpline services at NHS Trusts developing in the future? (Please consider future changes within the NHS as a whole organisation)	Free text box	
If you have any other comments about patient medicines helplines, or about the answers you have given in this survey, please use the space below.	Free text box	
Closing questions, for all respondents		
If you are happy to provide your job title, please enter this in the space below.	Free text box	

If you are happy to provide the name of your NHS Trust, please select it from the list below.	Drop-down list.	(List of all NHS Trusts in England, except Ambulance Trusts)
Would you potentially be interested in finding out about other research on this particular topic, carried out by the Pharmacy & Pharmacology Department at the University of Bath? This will involve receiving the occasional email about research being carried out by this specific research team only, and does not commit you to taking part. You can unsubscribe from receiving the information at any time. If so, please enter your email address below. Your email address will only be used to inform you of research studies, and will not be given to any third parties. Your contact details will not be stored alongside the other data you have provided.	Free text box	
Thank you for taking the time to complete this survey – your input is greatly appreciated. After reading this page, please click 'Finish', below, otherwise your answers will not be saved. Please tick the relevant boxes below, and if necessary provide your email address. Your email will only be used to inform you of the results and to contact you if you are randomly chosen to win the voucher, and will not be given to any third parties. Your contact details will not be stored alongside the other data you have provided.	Multiple choice, multiple response / free text box	I would like to be included in the prize draw. I would like to receive the results of the study when they become available.

Survey 2 questions and answer options

Question	Answer type	Answer options (if applicable)
Please read the following list and tick the options that you consider to be a major benefit or a minor benefit of providing a patient medicines helpline, based upon your experience. Leave any blank if you do not consider them to be a benefit.	Multiple choice, multiple response	Avoiding harm to patients (e.g., adverse effects, interactions). Identifying errors. Learning from patient experiences. Helping the organisation avoid complaints and possible litigation. Improving patient medication adherence. Supporting patient discharge. Providing assurance that patients can access professional advice at home. Improving the patient experience (e.g., patient satisfaction). Adhering to the NHS Constitution (e.g., patients have a right to information). Reducing visits to other healthcare services (e.g., GPs, A&E). Reducing medicines-related readmissions. Improvement in Trust targets and in national surveys (e.g., Adult Inpatient Survey). Optimising medicines.
Please use the space below if you have suggestions for other benefits of providing a patient medicines helpline which aren't on the list above.	Free text box	
How do you see patient medicines helplines at NHS Trusts developing in the future? (Please consider the future at your Trust, and future changes within the NHS as a whole organisation)	Free text box	
If you have any other comments about patient medicines helplines, or about the answers you have given in this survey, please use the space below.	Free text box	

Closing questions		
If you are happy to provide your job title, please enter this in the space below.	Free text box	
If you are happy to provide the name of your NHS Trust, please select it from the list below.	Drop-down list.	(List of all NHS Trusts in England, except Ambulance Trusts)
Would you potentially be interested in finding out about other research on this particular topic, carried out by the Pharmacy & Pharmacology Department at the University of Bath? This will involve receiving the occasional email about research being carried out by this specific research team only, and does not commit you to taking part. You can unsubscribe from receiving the information at any time. If so, please enter your email address below. Your email address will only be used to inform you of research studies, and will not be given to any third parties. Your contact details will not be stored alongside the other data you have provided.	Free text box	
Thank you for taking the time to complete this survey – your input is greatly appreciated. After reading this page, please click 'Finish', below, otherwise your answers will not be saved. Please tick the relevant boxes below, and if necessary provide your email address. Your email will only be used to inform you of the results and to contact you if you are randomly chosen to win the voucher, and will not be given to any third parties. Your contact details will not be stored alongside the other data you have provided.	Multiple choice, multiple response / free text box	I would like to be included in the prize draw. I would like to receive the results of the study when they become available.

Appendix 2: Search strategy for EMBASE (Study 2)

#1 'hotline'/exp AND ([embase]/lim OR [embase classic]/lim)

#2 hotline*:ti,ab OR 'hot$line*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#3 helpline*:ti,ab OR 'help$line*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#4 'telephone'/exp AND ([embase]/lim OR [embase classic]/lim)

#5 telephone*:ti,ab OR phone*:ti,ab AND ([embase]/lim OR [embase classic]/lim)

#6 'e-mail'/exp AND ([embase]/lim OR [embase classic]/lim)

#7 email*:ti,ab OR 'e-mail*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#8 'internet'/exp AND ([embase]/lim OR [embase classic]/lim)

#9 'internet*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#10 online:ti,ab AND ([embase]/lim OR [embase classic]/lim)

#11 webform*:ti,ab OR 'web$form*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#12 webpage*:ti,ab OR 'web$page*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#13 website*:ti,ab OR 'web$site*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#14 'web$based':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#15 'mobile application'/exp AND ([embase]/lim OR [embase classic]/lim)

#16 (((mobile NEXT/2 app):ti,ab) OR ((mobile NEXT/2 apps):ti,ab) OR ((mobile NEXT/2 application*):ti,ab)) AND ([embase]/lim OR [embase classic]/lim)

#17 'mobile device*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#18 ('social network*' OR twitter OR tweet* OR facebook OR 'instant messag*' OR 'SMS'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#19 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18

#20 'pharmacy'/exp AND ([embase]/lim OR [embase classic]/lim)

#21 'clinical pharmacy'/exp AND ([embase]/lim OR [embase classic]/lim)

#22 'hospital pharmacy'/exp AND ([embase]/lim OR [embase classic]/lim)

#23 'pharmacy school'/exp AND ([embase]/lim OR [embase classic]/lim)

#24 (pharmacy:ti,ab OR pharmacies:ti,ab) AND ([embase]/lim OR [embase classic]/lim)

#25 'pharmacist'/exp AND ([embase]/lim OR [embase classic]/lim)

#26 'pharmacy technician'/exp AND ([embase]/lim OR [embase classic]/lim)

#27 pharmacist*:ti,ab AND ([embase]/lim OR [embase classic]/lim)

#28 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27

#29 ((drug* OR medicine* OR medication*) NEAR/5 (information OR advice OR support OR enquir* OR inquir*)):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#30 #19 AND #28 AND #29

#31 (telepharmac*:ti,ab OR 'tele$pharmac*':ti,ab) AND ([embase]/lim OR [embase classic]/lim)

#32 ('epharmac*':ti,ab OR 'e$pharmac*':ti,ab) AND ([embase]/lim OR [embase classic]/lim)

#33 ((drug* OR medicine* OR medication*) NEAR/5 (hotline* OR hot$line*)):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#34 ((drug* OR medicine* OR medication*) NEAR/5 (helpline* OR help$line)):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#35 ((drug* OR medicine* OR medication*) NEAR/5 'call cent*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#36 ((drug* OR medicine* OR medication*) NEAR/5 'information cent*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#37 ((drug* OR medicine* OR medication*) NEAR/5 'information service*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#38 ((drug* OR medicine* OR medication*) NEAR/5 'information line*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#39 #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38

Appendix 3: Grey literature search strategy (Study 2)

Appendix S2. Grey literature search strategy

Godin et al. recommend applying a systematic approach when searching for grey literature (1). Following their recommendations, four grey literature sources were searched:

1) *Grey literature databases*. OpenGrey and ProQuest database for dissertations and theses were searched using the following search terms: 'medicines information', 'medicines helpline', 'drug information', and 'drug helpline'.

2) *Google and Google Scholar*. The Google search involved evaluating the relevance of all available hits when searching for the exact terms 'patient medicines helpline', 'medicines information centre', 'drug information helpline', 'drug information center', and 'drug information service'. The Google Scholar search involved evaluating the relevance of all available hits when searching for the exact terms 'patient medicines helpline', 'medicines information centre' , 'drug information helpline', 'drug information center', and 'drug information service', and then repeating the searches when limiting the terms to appearing in the title only. Limiting the search to 'title only' was recommended by Haddaway et al. (2), who conducted an evaluation using Google Scholar to search for grey literature in seven published systematic reviews.

3) *Targeted websites*. Websites of the following UK conferences were searched for conference proceedings: UK Medicines Information Practice Development Seminar (1998-2017), Royal Pharmaceutical Society Conference (formerly called British Pharmaceutical Conference; 1998-2017), Health Services Research and Pharmacy Practice Conference (1998-2018), and International Social Pharmacy Workshop (2004-2018).

4) *Consultation with experts*. Where possible, the main author of all included studies that were published within the last ten years were contacted, requesting details of any similar research already completed or being carried out, providing that a report of the findings was drafted.

References

1. Godin K, Stapleton J, Kirkpatrick SI, Hanning RM, Leatherdale ST. Applying systematic review search methods to the grey literature: A case study examining guidelines for school-based breakfast programs in Canada. *Systematic Reviews*. 2015;4(1).
2. Haddaway NR, Collins AM, Coughlin D, Kirk S. The role of Google Scholar in evidence reviews and its applicability to grey literature searching. *PLoS One*. 2015;10(9).

Appendix 4: Data extraction form (Study 2)

Source of study:

Title of study:

Author/s:

Year published:

Year of data collection:

Study design/s:

Type of service:

Number of participants/enquiries:

Outcomes:

Type of analysis:

Additional comments:

Appendix 5: Quality assessment and risk of bias table (Study 2)

Supplementary Table. Quality assessment and risk of bias in peer-reviewed published studies meeting eligibility criteria for the systematic review.

First author, Year published	Total [a]	RoB [b]	QoR	QoSD
Ansani, 2006	45% (9/20)	67% (4/6)	57% (4/7)	43% (3/7)
Badiani, 2017	50% (10/20)	50% (3/6)	57% (4/7)	43% (3/7)
Bramley, 2014	63% (12/19)	40% (2/5)	71% (5/7)	57% (4/7)
Bramley, 2018	55% (11/20)	50% (3/6)	86% (6/7)	29% (2/7)
Conner, 1980	41% (7/17)	33% (1/3)	14% (1/7)	57% (4/7)
Conner, 1982	29% (5/17)	67% (2/3)	29% (2/7)	29% (2/7)
Joseph, 2004	50% (10/20)	83% (5/6)	71% (5/7)	57% (4/7)
Marvin, 2011	65% (11/17)	67% (2/3)	71% (5/7)	71% (5/7)
Maywald, 2004	45% (9/20)	67% (4/6)	57% (4/7)	43% (3/7)
McInyk, 2000	30% (6/20)	83% (5/6)	43% (3/7)	29% (2/7)
McInyk, 2000	50% (10/20)	67% (4/6)	43% (3/7)	71% (5/7)
Muhammad, 1998	25% (5/20)	100% (6/6)	14% (1/7)	57% (4/7)
Olofinjana, 2009	60% (12/20)	50% (3/6)	86% (6/7)	43% (3/7)
Rutter, 2012	70% (14/20)	67% (4/6)	86% (6/7)	86% (6/7)
Smith, 1985	45% (9/20)	100% (6/6)	57% (4/7)	71% (5/7)
Williams, 2018 [c]	95% (19/20)	17% (1/6)	100% (7/7)	100% (7/7)

Abbreviations: RoB = risk of bias score (out of a maximum score of 6); QoR = quality of reporting score (out of a maximum score of 7); QoSD = quality of study design score (out of a maximum score of 7).

[a] Quality assessment was measured using the AXIS tool, developed by Downes et al. (2016). Depending on the study design, not all items were relevant. This accounts for the different possible maximum scores across studies.

[b] For the *Risk of Bias* subscale, the items were reversed so that higher scores in this table reflect greater potential for bias. However, the AXIS total score was calculated without reversing the *Risk of Bias* items, to ensure that the reported total score percentages reflect the amount of positively coded items in the tool. This accounts for the apparent discrepancy in this table between the total score and the sum of the subscales for each study.

[c] The study by Williams et al. (2018) was conducted by the authors of this systematic review. Quality assessment and risk of bias for this study was conducted by two postgraduate students who were independent of the study team.

Appendix 6: Search strategy for EMBASE (Study 3)

Appendix S1. Search strategy for EMBASE

#1 'hotline'/exp AND ([embase]/lim OR [embase classic]/lim)

#2 hotline*:ti,ab OR 'hot$line*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

#3 helpline*:ti,ab OR 'help$line*':ti,ab AND ([embase]/lim OR [embase classic]/lim)

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#22 'hospital pharmacy'/exp AND ([embase]/lim OR [embase classic]/lim)

#23 'pharmacy school'/exp AND ([embase]/lim OR [embase classic]/lim)

#24 (pharmacy:ti,ab OR pharmacies:ti,ab) AND ([embase]/lim OR [embase classic]/lim)

#25 'pharmacist'/exp AND ([embase]/lim OR [embase classic]/lim)

#26 'pharmacy technician'/exp AND ([embase]/lim OR [embase classic]/lim)

#27 pharmacist*:ti,ab AND ([embase]/lim OR [embase classic]/lim)

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#29 ((drug* OR medicine* OR medication*) NEAR/5 (information OR advice OR support OR enquir* OR inquir*)):ti,ab AND ([embase]/lim OR [embase classic]/lim)

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#31 (telepharmac*:ti,ab OR 'tele$pharmac*':ti,ab) AND ([embase]/lim OR [embase classic]/lim)

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#34 ((drug* OR medicine* OR medication*) NEAR/5 (helpline* OR help$line)):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#35 ((drug* OR medicine* OR medication*) NEAR/5 'call cent*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#36 ((drug* OR medicine* OR medication*) NEAR/5 'information cent*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#37 ((drug* OR medicine* OR medication*) NEAR/5 'information service*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#38 ((drug* OR medicine* OR medication*) NEAR/5 'information line*'):ti,ab AND ([embase]/lim OR [embase classic]/lim)

#39 #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38

Appendix 7: Grey literature search strategy (Study 2)

Appendix S2. Grey literature search strategy

Godin et al. recommend applying a systematic approach when searching for grey literature (1). Following their recommendations, four grey literature sources were searched:

1) *Grey literature databases*. OpenGrey and ProQuest database for dissertations and theses were searched using the following search terms: 'medicines information', 'medicines helpline', 'drug information', and 'drug helpline'.

2) *Google and Google Scholar*. The Google search involved evaluating the relevance of all available hits when searching for the exact terms 'patient medicines helpline', 'medicines information centre', 'drug information helpline', 'drug information center', and 'drug information service'. The Google Scholar search involved evaluating the relevance of all available hits when searching for the exact terms 'patient medicines helpline', 'medicines information centre' , 'drug information helpline', 'drug information center', and 'drug information service', and then repeating the searches when limiting the terms to appearing in the title only. Limiting the search to 'title only' was recommended by Haddaway et al. (2), who conducted an evaluation using Google Scholar to search for grey literature in seven published systematic reviews.

3) *Targeted websites*. Websites of the following UK conferences were searched for conference proceedings: UK Medicines Information Practice Development Seminar (1998-2017), Royal Pharmaceutical Society Conference (formerly called British Pharmaceutical Conference; 1998-2017), Health Services Research and Pharmacy Practice Conference (1998-2018), and International Social Pharmacy Workshop (2004-2018).

4) *Consultation with experts*. Where possible, the main author of all included studies that were published within the last ten years were contacted, requesting details of any similar research already completed or being carried out, providing that a report of the findings was drafted.

References

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2. Haddaway NR, Collins AM, Coughlin D, Kirk S. The role of Google Scholar in evidence reviews and its applicability to grey literature searching. *PLoS One*. 2015;10(9).

Appendix 8: Data extraction form (Study 3)

Source of study:

Title of study:

Author/s:

Year published:

Year of data collection:

Study design/s:

Type of service:

Number of participants/enquiries:

Outcomes:

Type of analysis:

Additional comments:

Appendix 9: Participant characteristics (Study 4)

Supplementary Table 1. Participant characteristics (detailed)

Participant number	Gender	Job title	Years employed as a pharmacy professional	Years operating a PMHS	NHS Trust type
P1	Female	Lead MI Pharmacist	35	8	Acute
P2	Female	Lead MI Pharmacist	6	6	Acute
P3	Female	MI Manager	21	6	Acute
P4	Male	Chief Pharmacist	30	6	Acute
P5	Male	Lead MI Pharmacist	10	4	Acute
P6	Female	Lead MI Pharmacist	14	7	Acute
P7	Female	MI Pharmacist	6	2	Acute
P8	Male	Pharmacist	3	6 months	Acute
P9	Female	Chief Pharmacist	18	9	Specialist
P10	Female	Lead MI Pharmacist	7	6	Acute
P11	Female	MI Pharmacist	4	2	Acute
P12	Female	Pharmacist	23	5	Mental health
P13	Female	Senior MI Pharmacist	19	10	Acute
P14	Female	Chief Pharmacist	33	5	Acute
P15	Female	MI Manager	25	10	Acute
P16	Male	Pharmacist	3	9 months	Mental health
P17	Female	Lead MI Technician	26	3.5	Integrated
P18	Female	Chief Pharmacist	37	4	Integrated
P19	Female	MI Pharmacist	3	1	Acute
P20	Female	Lead Pharmacist	20	12	Specialist
P21	Female	Lead MI Pharmacist	15	1.5	Acute
P22	Male	Senior MI Pharmacist	19	5	Acute
P23	Female	Lead MI Pharmacist	8	5	Acute
P24	Female	Lead MI Pharmacist	22	7	Acute
P25	Female	Lead MI Pharmacist	7	5.5	Acute
P26	Female	Lead MI Pharmacist	13	5	Acute
P27	Male	Lead MI Pharmacist	15	2	Community
P28	Female	Lead MI Pharmacist	12	3	Acute
P29	Female	MI Pharmacist	21	19	Acute
P30	Female	Senior Pharmacist	28	5	Mental health
P31	Male	Junior Pharmacist	3	2.5	Acute
P32	Female	Lead MI Pharmacist	17	7	Acute
P33	Male	MI Manager	7	2	Acute
P34	Female	Senior MI Pharmacist	6	3	Acute

Note. Abbreviations: PMHS = patient medicines helpline service; MI = medicines information; NHS = National Health Service.

Appendix 10: Interview schedule (Study 4)

Q1	**To begin, could you please tell me about your role within your NHS Trust's Pharmacy Services?**
Q2	**Please could you tell me about your role in relation to the patient medicines helpline service?**
	Probe – [For pharmacists, not chief pharmacists] Please could you tell me your responsibilities in terms of the patient medicines helpline? Probe – [For both pharmacists and chief pharmacists] Did you help to set up the patient medicines helpline? If so, please could you describe what your involvement was in setting the service up?
Q3	**Please could you describe why your patient medicines helpline service was developed?**
	Probe – Research studies? Guidelines? (If so, which?) Awareness of national standards? Probe – What do you consider to be the purpose of the patient medicines helpline service? (Has its purpose changed over time? If so, in what ways? And Why?)
Q4	**Please could you tell me your thoughts about your patient medicines helpline service?**
	For example, meeting its aims. Probe - Is there anything you'd like to say about the cost of running the service? Probe - Is there anything you'd like to say about how the service may have developed since it first began?
Q5	**Please could you tell me what you consider to be the positive aspects of operating a patient medicines helpline service?**
	For example… Probe – Aspects that are positive for service users. Probe – Aspects that are positive for you/the MI team (e.g., learning from adverse patient experiences). Probe – Aspects that are positive for the hospital/NHS Trust (e.g., learning from adverse patient experiences; service improvement initiatives as a result of operating a PMH). Probe – Are there any other positive aspects of operating your patient medicines helpline which you haven't mentioned so far?
Q6	**Please could you tell me about any challenges of operating a patient medicines helpline service?**
	For example… Probe – Aspects that are negative/unhelpful/risks/safety issues for service users. Probe – Aspects that are negative/unhelpful for you/the MI team Probe – Aspects that are negative/unhelpful for the hospital/NHS Trust. Probe – Are there any other challenges of operating your patient medicines helpline service which you haven't mentioned so far?
Q7	**Please can you tell me your thoughts regarding whether the patient medicines helpline service meets the needs of patients and carers?**
	For example, their medicines information needs; their support needs. Probe – Please could you explain why?/why not? Probe – Is there anything you'd like to say about the uptake of the service? (If they mention lack of use: Probe - Do you have any suggestions as to why this might be? Probe – Lack of promotion; lack of need; use of other services (if so, which?)). Probe – Is there anything you'd like to say about the types of patients/people who use

	the service? Probe – Are there any types of patients/people who you think could benefit from the service but who don't typically use it? (If so, who? And why?)
(If not already known from previous answers)	
Q8	**Can you tell me your thoughts regarding the cost-effectiveness of the patient medicines helpline?**
	Probe – *(If not already known)* Please could you say how your helpline service is funded?
Q9	**Please could you tell me about any aspects of your patient medicines helpline service that you think could be improved?**
	Probe - If so, why? / In what way? *For example….* Probe – Service user access. (Alternative methods? Online chat? Email? Skype / facetime?) Probe – Helpline availability. Probe – Helpline promotion. Probe – Procedures you use (e.g., documenting the calls; use of a SOP). Probe –IT systems and technology you use. Probe – Service user involvement (e.g., including feedback/satisfaction surveys). Probe – Mechanisms to feed back to the Trust any issues/errors which become apparent during the operation of the service. Probe – (If not already mentioned) Are you aware of the national standards which are available for operating a patient medicines helpline service? Have you used them to develop your service? If so, in what ways?
Q10	**Research suggests that sometimes people contact a patient medicines helpline service if there is an error with their medicines. Please could you describe any process that occurs if a helpline call reveals that an error has been made with a patient's medicines?**
	Probe – Learning from errors / Service improvement initiatives.
Q11	**In what ways do you think the helpline service could be used to improve practice, within Pharmacy Services and the wider organisation?**
	Probe – For example, if data is routinely collected about errors, using that information to improve practice. Probe – [If not yet known] Based upon the examples you've given, are these means of improvement used at your hospital to improve practice?
Q12	**What qualities do you perceive to be important in order to provide a successful patient medicines helpline service?**
	Probe – (if not obvious) Why are these things important? Probe – What staff skills are important? (Training? Standard operating procedures?)
Q13	**How do you see patient medicines helplines at NHS Trusts developing in the future?**
	Probe – Developing the service at your NHS Trust, specifically (e.g., additional ways of accessing the service; availability of the service; promotion; procedures; IT/technology to provide the service; service user involvement). Probe – Developments within the UK generally (e.g., move towards regional/shared services - Carter Report / 5 year forward review / sustainability and transformation plans). Probe – Any perceived financial/funding issues in the future.

Q14	**In what ways is local knowledge needed in order to deal with helpline enquiries? By 'local knowledge', I mean knowledge that is available at your hospital or NHS Trust only (e.g., patient records, local policies and procedures, advice from clinicians who cared for the patient).**
	Probe – patient records; access to relevant clinical staff; local policies and procedures.
Q15	**What do you think the impact would be if patient medicines helpline services became regional or national in the future, instead of local to hospitals?**
	Probe – Impact of this upon the service / quality of the service / the type of information that could be provided?
Q16	**Those are all of the questions that I have about patient medicines helpline services. Although, is there anything else which you would like to say about patient medicines helpline services, which you feel would be important to share at this point?**

Appendix 11: Interview schedules (Study 5)

Interview schedule for patients

Q1	**For background information, please could you tell me about your recent admission/period of care?**
	For example, please could you tell me why you were admitted? / why were you receiving care? *Probe* – For how long were you admitted? *Probe* – Please could you tell me about any other hospital admissions you may have had recently? (timeframe – past 2 months)
Q2	**Prior to using the helpline service recently, please can you tell me what you would typically do if you had a question or concern with your medicines?**
	For example, your GP, or a community pharmacist, or NHS 111 or NHS Direct. *Probe* – Have you used the patient medicines helpline service in the past? If so, what was your experience of using the helpline previously?
Q3	**How did you hear about the medicines helpline service?**
Q4	**Please could you tell me why you contacted the medicines helpline service on *[date]*?**
	[Additional questions about the medicines issue/query…] *Probe* – Please could you tell me about the medicine or medicines you were concerned about? (e.g., what it was; what it is for; what your concerns were). *Probe* – How did you feel about your medicines before you contacted the medicines helpline service? *Probe* - What impact (if any) did this issue *[use their words]* have upon you before you contacted the medicines helpline service and spoke to a pharmacist? (e.g., Physical symptoms, Anxiety/worry/stress, Inconvenience, Not taking medicines as prescribed) *Probe* – Please can you tell me your thoughts about the seriousness of the issue/situation *[use their words]*? (and why) *Probe* – Was there anything else you contacted the medicines helpline service about? (If so, what?) ***[Additional questions about their circumstances…]*** *Probe* – Can you tell me about anyone who encouraged you to contact the medicines helpline service? For example, who this was, and why they encouraged you to do this. ***[Additional questions about other sources of information…]*** *Probe* – Please can you tell me about any other sources of information that you may have considered using? For example, what these were, and why you didn't use these. Why you contacted the medicines helpline instead. (Or if you did use any other sources of information before contacting the helpline service, what were your experiences of using them?). What are the advantages of the helpline service compared to the other options you considered?
[If a medicines-related error has been disclosed, go to Q5. If not, go to Q6]	
Q5	**You said that there was an error with your medicines/omission/lack of information or instructions *[use their words]*. Please can you tell me about this?**
	Probe – What was the error/omission/lack of instructions? *Probe* - How did you realise that there was an error/omission/lack of instructions? *Probe* – *When* did you realise that there was an error/omission/lack of instructions?

	Probe - How did you feel when you realised that there was an error/omission/lack of instructions? (How did you react?) *Probe* – Has this issue been fully resolved? If so, how? *Probe* - How do you feel about this issue now?
Q6	**Please can you tell me about the conversation you had with the pharmacist when you contacted the helpline?**
	Probe - How well did you feel that the pharmacist understood your query/concern/issue? *Probe* - What did they say or do to make you feel this way?
[If not already known from the previous question…]	
Q7	**Please could you describe what information or advice the pharmacist gave you when you contacted the helpline service?**
	Probe – How well did you understand the information that the pharmacist gave you during the call? (What about your understanding of the information by the end of the call?) Probe - Was there anything else that the pharmacist said to you? (If so, what?) Probe - How did you feel about the information/advice you received from the pharmacist? Probe – Was anything left unresolved? If so, what? Why was it left unresolved? *Probe* – How did you feel directly after using the helpline service? (e.g., worried/anxious, reassured, relieved?) If so, why?
Q8	**Please can you tell me your thoughts about the medicines helpline service?**
	For example, could you tell me about … – what it was like accessing the service? (e.g., time taken to get through to the service; whether you had to call back? (if so, how was this?); whether you had to leave a message and someone got back to you? (if so, how was this?)) – the pharmacist? – the time taken to answer your enquiry? – the amount of information you received? (e.g., was it enough? Too much?) – the advertisements for the service? *Probe* - Why were these particular aspects *[use their words]* <u>helpful</u> to you? *Probe* - Why were these particular aspects *[use their words]* <u>unhelpful</u> to you? Could you tell me about any other aspects of the service that you may have found to be either helpful or unhelpful?
Q9	**Please can you tell me your thoughts about *improving* the helpline service?**
	Probe – If you could change the service in any way, to make it more useful for you and other people, how would you change it? (And why?) *[The probes for the previous question may be relevant here]* Can you think about any other useful ways in which you would have liked to communicate with the medicines information service? (Why would these be useful?) For example, online chat / Skype / email.
Q10	**How have things been for you in the *XX* weeks since you used the helpline service?**
	Probe – Can you tell me about any other sources that you may have used to get information or advice about your medicines, since contacting the medicines helpline service? (For example, your GP, another pharmacist, online?)
[If not already known from the previous questions…]	
Q11	**Please can you tell me about any changes to your medicines since you contacted the helpline service?**
	For example, can you tell me about how you were taking your medicines before you contacted the helpline? Can you tell me about how you are taking your medicines now?

	[Check if changes are in accordance with the advice from the pharmacist. If they aren't, check why]. *Probe* – What were your reasons for making this change? *Probe* – What effects (if any) has this change to your medicines had? (e.g., any positive effects; any downsides as a result of the change) Please can you tell me what you think about the safety of your medicines? (Probe how this was before the helpline use compared to afterwards)
[If not already known from the previous question…]	
Q12	**Please can you tell me about any changes to your health since you contacted the medicines helpline service?**
	Probe for any positive and negative changes *Probe* - If so, what changes? (If not, do you think there will be changes on your health? If so, in what ways?)
[If not already known from the previous questions…]	
Q13	**Please tell me about any other changes you may have experienced since you contacted the medicines helpline service?**
	For example, regarding your understanding of your medicines.
Q14	**How do you currently feel about your medicine/s?**
Q15	**How do you currently feel about the hospital or NHS Trust where you recently received care?**
(If not already known…)	
Q16	**What would you have done about this issue *[use their words]*, had the helpline service not been available?**
	Probe – Please can you tell me what you think would have happened had you not contacted the helpline service? (Try to probe for their thoughts about avoided harm). *Probe* – Please could you tell me the reason why you would've instead *[use their words, e.g., 'gone to your gp']* about this particular issue rather than any other source of support? *Probe* – What would you have done if the helpline service was operated from another NHS Trust in the region to the one where you recently received care? (Probe why) *Probe* – What would you have done if the helpline service was a national helpline, instead of local to you? (Probe why)
Q17	**Those are all of the questions that I have about your recent use of the patient medicines helpline service. Although, is there anything else which you would like to say about your use of the medicines helpline service, which you feel would be important to share at this point?**

Interview schedule for carers

Q1	**Prior to using the helpline service recently, please can you tell me what you would typically do if you had a question or concern about medicines?**
	For example, a GP, or a community pharmacist, or NHS 111 or NHS Direct. *Probe* – Have you used the patient medicines helpline service in the past? If so, what was your experience of using the helpline previously?
Q2	**How did you hear about the medicines helpline service?**

Q3	**Could you please tell me why you contacted the medicines helpline service on *[date]*?**
	[Additional questions about the medicines issue/query…] *Probe* – How did you feel about the medicines before you contacted the medicines helpline service? *Probe* – What impact (if any) did this issue *[use their words]* have before you contacted the medicines helpline service and spoke to a pharmacist? *Probe* – Please can you tell me your thoughts about the seriousness of the issue/situation *[use their words]*? (and why) *Probe* – Was there anything else you contacted the medicines helpline service about? (If so, what?) ***[Additional questions about other sources of information…]*** *Probe* – Please can you tell me about any other sources of information that you may have considered using? For example, what these were, and why you didn't contact these. Why you contacted the medicines helpline instead. (Or if you did use any other sources of information before contacting the helpline service, what were your experiences of using them?). What are the advantages of the helpline service compared to the other options you considered?
[If a medicines-related error has been disclosed, go to Q4. If not, go to Q5]	
Q4	**You said that there was an error with the patient's medicines/omission/lack of information or instructions *[use their words]*. Please can you tell me about this?**
	Probe – What was the error/omission/lack of instructions? *Probe* - How did you realise that there was an error/omission/lack of instructions? *Probe* – *When* did you realise that there was an error/omission/lack of instructions? *Probe* - How did you feel when you realised that there was an error/omission/lack of instructions? (How did you react?) *Probe* – Has this issue been fully resolved? If so, how? *Probe* - How do you feel about this issue now?
Q5	**Please can you tell me about the conversation you had with the pharmacist when you contacted the helpline?**
	Probe - How well did you feel that the pharmacist understood your query/concern/issue? *Probe* - What did they say or do to make you feel this way?
[If not already known from the previous question…]	
Q6	**Please could you describe what information or advice the pharmacist gave you when you contacted the helpline service?**
	Probe – How well did you understand the information that the pharmacist gave you during the call? (What about your understanding of the information by the end of the call?) Probe - Was there anything else that the pharmacist said to you? (If so, what?) Probe - How did you feel about the information/advice you received from the pharmacist? Probe – Was anything left unresolved? If so, what? Why was it left unresolved? *Probe* – How did you feel directly after using the helpline service? (e.g., worried/anxious, reassured?) If so, why?
Q7	**Please can you tell me your thoughts about the medicines helpline service?**
	For example, could you tell me about … – what it was like accessing the service? (e.g., time taken to get through to the service; whether you had to call back? (if so, how was this?); whether you had to leave a message and someone got back to you? (if so, how was this?)) – the pharmacist? – the time taken to answer your enquiry? – the amount of information you received? (e.g., was it enough? Too much?) – the advertisements for the service?

	Probe - Why were these particular aspects *[use their words]* helpful to you? *Probe* - Why were these particular aspects *[use their words]* unhelpful to you? Could you tell me about any other aspects of the service that you may have found to be either helpful or unhelpful?
Q8	**Please can you tell me your thoughts about *improving* the helpline service?**
	Probe – If you could change the service in any way, to make it more useful for you and other people, how would you change it? (and why?) *[The probes for the previous question may be relevant here]* Can you think about any other useful ways in which you would have liked to communicate with the medicines information service? (Why would these be useful?)
Q9	**How have things been in the *XX* weeks since you used the helpline service?**
	Probe – Can you tell me about any other sources that you may have used to get information or advice about the medicines, since contacting the medicines helpline service? (For example, a GP, another pharmacist, online?)
[If not already known from the previous questions…]	
Q10	**Please can you tell me about any changes to the medicines since you contacted the helpline service?**
	Probe – What were the reasons for making this change? *Probe* – What effects (if any) has this change to the medicines had? (e.g., any positive effects; any downsides as a result of the change) Please can you tell me what you think about the safety of the medicines? (Probe how this was before the helpline use compared to afterwards)
[If not already known from the previous questions…]	
Q11	**Please tell me about any other changes you may have experienced since you contacted the medicines helpline service?**
	For example, regarding your understanding of the medicines.
Q12	**How do you currently feel about the medicines being taken by *[the person you care for]*?**
Q13	**How do you currently feel about the hospital or NHS Trust?**
(If not already known…)	
Q14	**What would you have done about this issue *[use their words]*, had the helpline service not been available?**
	Probe – Please can you tell me what you think would have happened had you not contacted the helpline service? (Try to probe for their thoughts about avoided harm). *Probe* – Please could you tell me the reason why you would've instead *[use their words, e.g., 'gone to your gp']* about this particular issue rather than any other source of support? *Probe* – What would you have done if the helpline service was operated from another NHS Trust in the region to the one where you recently received care? (Probe why) *Probe* – What would you have done if the helpline service was a national helpline, instead of local to you? (Probe why)
Q15	**Those are all of the questions that I have about your recent use of the patient medicines helpline service. Although, is there anything else which you would like to say about your use of the medicines helpline service, which you feel would be important to share at this point?**

Appendix 12: Participant characteristics (Study 5)

Supplementary Table. Participant characteristics (detailed)

Participant number	Caller type	Gender	Age range	Occupational status	NHS Trust type
P1	Carer	Female	50-59	Carer and/or homemaker	Acute
P2	Patient	Male	60-69	Retired	Acute
P3	Patient	Male	80-89	Retired	Acute
P4	Carer	Female	70-79	Retired	Acute
P5	Patient	Female	50-59	Unemployed	Acute
P6	Patient	Female	60-69	Unemployed	Mental Health
P7	Patient	Female	70-79	Retired	Acute
P8	Patient	Male	80-89	Retired	Acute
P9	Patient	Female	70-79	Retired	Acute
P10	Patient	Female	70-79	Retired	Acute
P11	Carer	Male	70-79	Retired	Acute
P12	Patient	Female	70-79	Retired	Acute
P13	Carer	Female	50-59	Retired	Acute
P14	Patient	Female	60-69	Retired	Acute
P15	Patient	Male	70-79	Retired	Acute
P16	Patient	Female	50-59	Employed	Acute
P17	Patient	Female	60-69	Employed	Acute
P18	Patient	Male	70-79	Retired	Acute
P19	Patient	Female	60-69	Retired	Acute
P20	Patient	Male	70-79	Retired	Acute
P21	Patient	Male	60-69	Retired	Acute
P22	Patient	Female	70-79	Retired	Acute
P23	Patient	Male	50-59	Retired	Acute
P24	Patient	Male	80-89	Retired	Acute
P25	Patient	Male	70-79	Retired	Acute
P26	Patient	Female	70-79	Retired	Acute
P27	Patient	Female	50-59	Employed	Acute
P28	Patient	Female	70-79	Retired	Acute
P29	Patient	Male	80-89	Retired	Specialist
P30	Carer	Male	70-79	Retired	Acute
P31	Patient	Male	70-79	Retired	Acute
P32	Carer	Female	50-59	Carer and/or homemaker	Acute
P33	Patient	Female	70-79	Retired	Acute
P34	Patient	Female	60-69	Retired	Acute
P35	Patient	Male	40-49	Unemployed	Acute
P36	Carer	Female	70-79	Retired	Acute
P37	Patient	Male	40-49	Employed	Acute
P38	Patient	Female	70-79	Retired	Acute
P39	Patient	Male	70-79	Retired	Acute
P40	Patient	Female	40-49	Unemployed	Acute

Note. Abbreviations: NHS = National Health Service.